Nitroglycerin infusion after percutaneous coronary intervention does not influence short- and long-term outcome – a prospective NAPI (Nitroglycerin Administration after Percutaneous Intervention)* study

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Abstract

Background: Although the benefit of nitroglycerin infusion in patients after elective coronary angioplasty has not been established, this regimen is routinely used in some centres.

Aim: The Nitroglycerin Administration after Percutaneous Intervention (NAPI) study tested the efficacy of routine nitroglycerin infusion on the 1st day after percutaneous coronary intervention (PCI) in a double-blind randomised single-centre clinical trial.

Methods. We randomly assigned 200 patients scheduled for elective PCI to treatment with nitroglycerin (100 patients, age 58±6 years, infusion up to 100 µg/min) or placebo (100 patients, age 57±5 years, p=NS, NaCl 0.9%) for 12 hours after PCI. Patients with acute myocardial infarction, haemodynamic instability during PCI and known intolerance to nitrates were excluded. Patients who were randomised to the placebo group had the possibility to receive nitroglycerin infusion according to the attending physician's decision. Clinical endpoints (cardiac death, myocardial infarction, postprocedural chest pain, unstable angina and repeated PCI) were assessed in hospital and out of hospital with follow-up extended to 24 months.

Results: There were no differences during in-hospital stay between those receiving nitroglycerin and receiving placebo, regarding mortality (0 vs. 0%, NS), myocardial infarction (0 vs. 2%, NS), postprocedural chest pain (10 vs. 8%, NS) or repeated PCI (0 vs. 2%, NS). Similarly, 24-month follow-up also revealed no significant differences between those receiving nitroglycerin and placebo (mortality: 0 vs. 0%, NS; myocardial infarction: 4 vs. 4%, NS; repeated PCI: 10 vs. 8%, NS or CABG: 0 vs. 0%, NS).

Conclusions: Routine use of intravenous nitroglycerin after elective PCI has no influence on in-hospital and long-term outcome, including cardiac death, myocardial infarction, postprocedural chest pain, unstable angina and repeated PCI.

Key words: elective PCI, nitrates, percutaneous coronary angioplasty

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Introduction

Nitroglycerin has been used for the relief of angina for more than 100 years. In the prethrombolytic era, it was shown to reduce mortality rates in acute myocardial infarction (MI) as well as reducing the size, expansion and complications of infarction [1, 2]. A variety of pharmacological properties which improve the myocardial oxygen supply-to-demand ratio, especially in ischaemic zones of the heart, have been implicated in these effects [3-7]. Furthermore, nitroglycerin is effective in suppressing coronary vasospasm because of its primary effect as a smooth muscle relaxant. It increases coronary blood flow to hypoperfused regions selectively by a vasodilatory effect on the epicardial conductance vessels and by increasing the collateral flow [3-5, 7]. These properties might also be useful in the early stage after percutaneous coronary intervention (PCI).

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Our aim was to test the effects of routine nitroglycerin infusion on the incidence of anginal chest pain during the 24 hours after PCI and short-term in-hospital outcome, including mortality, MI, repeated PCI and PCI-related complications in a prospective double-blind randomised single-centre trial NAPI (Nitroglycerin after Percutaneous Intervention) study. In addition, 24-month follow-up data were analysed to find out whether routine postprocedural nitroglycerin infusion had any influence on long-term clinical outcome, such as the occurrence of death, MI, repeated PCI or CABG.

Methods

Patients

The study group comprised 200 patients, who were recruited from a series of consecutive 319 patients with chronic stable angina scheduled for elective PCI between 01.10.2001 and 02.03.2002. The main reasons for patients not being enrolled were ingestion of long-acting nitrates within the previous 24 hours before the procedure and missing informed consent. Informed consent was obtained from each patient and the study protocol followed to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the local human research committee. Baseline characteristics and drug therapy of enrolled patients are presented in Table I.

Table I. Baseline characteristics and treatment of the studied groups

Baseline characteristics	Nitroglycerin (n=100)	Placebo (n=100)	p
Age [years]	58±6	57±5	NS
Male gender	64 (64%)	58 (58%)	NS
History of myocardial infarction	64 (64%)	74 (74%)	NS
History of smoking	54 (54%)	66 (66%)	NS
Hypertension	56 (56%)	50 (50%)	NS
Hypercholesterolaemia	66 (66%)	59 (59%)	NS
Diabetes mellitus	10 (10%)	12 (12%)	NS
Preprocedural medication			
Angiotensin converting enzyme inhibitors	80 (80%)	43 (86%)	NS
Acetylsalicylic acid	100 (100%)	100 (100%)	NS
Beta-blockers	76 (76%)	80 (80%)	NS
Calcium antagonists	20 (20%)	22 (22%)	NS
Nitrates	30 (30%)	34 (34%)	NS
Ticlopidine	90 (90%)	96 (96%)	NS
Statins	56 (56%)	60 (60%)	NS

The patients were randomly assigned to treatment with nitroglycerin (100 patients, age 58±6 years) or placebo (control group, 100 patients, age 57±5 years, NS). Patients with acute MI, known intolerance to nitrates, clinical indications for nitroglycerin such as uncontrolled hypertension or chest pain directly after PCI, and those with haemodynamic instability during PCI, were excluded. Procedural characteristics of the studied groups are presented in Tables II and III.

Treatment protocol

Sets of identically labelled 50 ml vials containing either nitroglycerin (1 mg/ml, glycerol trinitrate) or placebo (0.9% saline) were prepared by the hospital pharmacy. Randomisation was performed before the revascularisation procedure and the code was not broken until the final analyses. Study medication was delivered immediately after revascularisation by continuous intravenous infusion pump at an initial dose corresponding to 50 µg/min of nitroglycerin. After 30 minutes, infusion speed was increased to the dose of 100 µg/min of nitroglycerin and continued under blood

Table II. Procedural characteristics (1) of the studied groups

	Nitroglycerin	Placebo	P
Single-vessel disease	54 (54%)	50 (50%)	NS
Multivessel disease	46 (46%)	50 (50%)	NS
Target lesion			
Left anterior descending artery	40 (40%)	44 (44%)	NS
Circumflex artery	26 (26%)	24 (24%)	NS
Right coronary artery	42 (42%)	38 (38%)	NS
% stenosis before percutaneous coronary intervention	89±5%	92±7%	NS
Plain balloon angioplasty	28 (28%)	30 (30%)	NS
Elective stenting	72 (72%)	70 (70%)	NS
Multivessel angioplasty	12 (12%)	14 (14%)	NS
Complete revascularisation	66 (66%)	64 (64%)	NS

Table III. Procedural characteristics (2) of the studied groups

Procedure success rate	Nitroglycerin	Placebo	P
Less than 10% residual stenosis (QCA)	96 (96%)	94 (94%)	NS
More than 20% residual stenosis	6 (6%)	8 (8%)	NS
Stent implantation	79 (79%)	81 (81%)	NS
Use of abciximab	14 (14%)	16 (16%)	NS

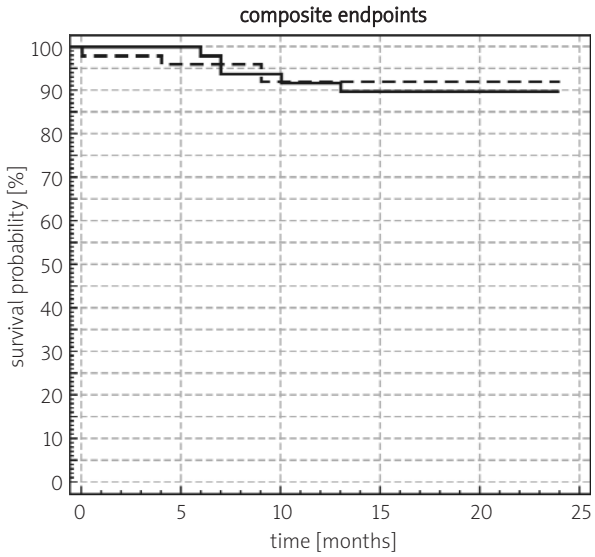

Figure 1. Analysis of survival using the Kaplan-Meier method. Solid line – nitroglycerin group; dashed line – placebo group

pressure control for 12 hours. In the control group, nitroglycerin could be initiated during this period at the discretion of attending physicians if coronary chest pain occurred. Antiplatelet therapy was initiated just after PCI.

Outcome measures

Clinical endpoints were defined as the occurrence of anginal chest pain within 24 hours after the procedure, death, repeated PCI, postprocedural MI and PTCA-related complications during in-hospital stay (mean value – 3 days). Physicians who filled in patients' study questionnaires were unaware of the randomisation results.

Anginal chest pain was defined as retrosternal discomfort, which was judged by the attending physician not to be from a non-cardiac source (for example, chest wall pain upon palpation or gastroesophageal reflux responsive to antiacid drugs). PCI- and stenting-related complications (death, MI, emergency aorto-coronary bypass grafting or major bleeding) and the need for repeat angiography within 24 hours were recorded. Periprocedural MI was defined as a postprocedural rise of the creatine kinase concentration (CK) above twice the upper limit (with 10% CK-MB), accompanied by chest pain or electrocardiographic changes.

We repeated follow-up 24 months after PCI to find out whether the study medication had any influence on the occurrence of death, MI, repeated PCI or CABG during long-term follow-up.

Table IV. Incidence of outcome measures during in-hospital period

Endpoints	Total	Nitroglycerin	Placebo	p
Anginal chest pain during 24 hours after PCI	18	10 (10%)	8 (8%)	NS
Repeated PCI	2	0	2 (2%)	NS
Postprocedural myocardial infarction	2	0	2 (2%)	NS
Deaths	0	0	0	NS
PCI related complications	0	0	0	NS
Any endpoint	22	10 (10%)	12 (12%)	NS

Statistical analysis

The results are presented as mean ± SD or percentages. Statistical analysis was performed on an intention-to-treat basis, irrespective of total dose of the study medication delivered. The distribution of variables was compared using the χ^2 test. Values of $p < 0.05$ were considered significant. Analysis of survival was performed using the Kaplan-Meier method (Figure 1).

Results

All enrolled patients completed the follow-up period. Ten control patients received nitroglycerin at the discretion of the attending physician (cross-over) because of elevated blood pressure (4 patients) or coronary chest pain (6 patients). Their baseline characteristics, drug therapy and procedural characteristic are shown in Tables I-III.

Adverse events tended to be more frequent in patients treated with nitroglycerin although the differences did not reach statistical significance. The most frequent side effect was hypotension <90 mmHg, which occurred in 22 (22%) patients treated with nitroglycerin compared with 10 (10%) control patients (NS). Severe hypotensive response, defined as a minimal systolic blood pressure during study medication treatment of <80 mmHg, occurred in 10 patients from the nitroglycerin group and in 4 controls (NS). Most of these events could be attributed to insufficient fluid substitution or to exaggerated vagal reactions upon withdrawal of the femoral sheaths, and were rapidly corrected with either saline infusion or atropine. No further complications associated with these events were noted. The mean delivered total dose of nitroglycerin was 65±15 mg. Self-assessed symptoms during the observation period were not related to the assigned treatment except for more frequent headache. A summary of outcome measures is presented in Table IV.

The incidence of retrosternal pain was very low, consistent with the high percentage of successful

procedures, and there were no differences between the two studied groups. Eighteen patients, ten from the nitroglycerin group and eight controls, suffered from retrosternal pain during the in-hospital period. Fourteen of them had CK and CK-MB levels within the normal range. Four of them (2 in each group) had CK-MB elevation 1.5 times above the upper normal level. PCI-related complications (MI, emergency aorto-coronary bypass grafting, major bleeding or death) did not occur in either group.

Two repeat angiography examinations were necessary in the control group followed by repeated PCI because of in-stent thrombosis, which occurred within 24 hours after the initial procedure. There were no significant differences between the two groups concerning postprocedural pharmacotherapy. Every patient received aspirin and most of them angiotensin-converting enzyme inhibitors (80 vs. 86%, NS), ticlopidine (90 vs. 96%, NS) and beta-blockers (76 vs. 80%, NS) (Table I).

During the long-term follow-up (24 months) no patient died. The composite end-point (the presence of any serious clinical event – death, MI or coronary revascularisation) occurred in 10% of patients treated with nitroglycerin and 8% of controls (NS). Four patients from the nitroglycerin group and four controls developed acute MI. Ten patients who received nitroglycerin and four controls had repeated PCI (NS). A summary of the outcomes is presented in Table V and survival curves are shown in Figure 1.

Table V. Incidence of outcome measures during 24-month follow-up

Endpoints	All	Nitroglycerin	Placebo	p
Deaths	0	0	0	NS
Myocardial infarction	8	4	4	NS
Repeated PCI	18	10	8	NS
CABG	0	0	0	NS
Composite endpoint	18	10	8	NS
Total number of endpoints	26	14	12	NS

Discussion

We performed this double-blind, randomised study to examine the effects of intravenous nitroglycerin on short- and long-term clinical events after PCI. The main conclusion of our study is that routine administration of nitroglycerin after PCI in a stable patient has no impact on the short- and long-term clinical course. This has not been studied in a randomised trial to date. Low mortality (0%), which was observed in both groups during 24-month follow-up, is typical for elective PCI in stable patients. In our study it was a consequence of the high rate of successful PCI procedures (96 vs. 94%, NS) defined as TIMI-3 flow grade and <10% residual restenosis. Our results also showed no correlation between the use of intravenous nitroglycerin and the frequency of repeated coronary intervention and CABG.

The incidence of repeated PCI was low, 2% in both groups, and no patient in our group required CABG. The rate of procedures with residual stenosis greater than 20% of lumen diameter was also very low (4 vs. 6%, NS).

Another predefined endpoint was postprocedural MI, both during the in-hospital period and later, during the 24-month observation period. Postprocedural CK elevation consistent with infarction may develop due to peripheral embolisation by plaque material or thrombus, developing after PCI or stent implantation [8]. In fact, non-Q-wave MI is reported in 8% to 15% of patients undergoing PCI [9]. No patient in our study developed MI after the PCI procedure during hospitalisation. Platelet glycoprotein IIb/IIIa receptor inhibitors have been shown to remarkably reduce the incidence of postprocedural MI, and the use of these agents has become accepted in the management of complicated PCI, but their use in our study was relatively low. Thirty patients in the study received periprocedural abciximab with no significant difference between the two groups. Abciximab was given at the discretion of the operator when the procedure was regarded as associated with high risk.

Zvara et al. [10] showed that prophylactic administration of intravenous nitroglycerin had no influence on the incidence of MI in patients undergoing CABG. The ISIS-4 and GISSI-3 trials showed no prognostic benefit of treating acute MI with nitroglycerin. The drug has been generally viewed as having purely symptomatic indications for the relief of chest pain. Kurz et al. [1] performed a single-centre study comparing the in-hospital outcome between patients treated with intravenous nitroglycerin or placebo. However, their study was focused strictly on postprocedural chest pain and minor myocardial necrosis and their follow-up was limited to the in-hospital period only. In our trial, we predefined more endpoints, including postprocedural chest pain, mortality, MI, repeated PCI and CABG. We also extended our follow-up to 24 months after the procedure to find out whether routine postprocedural nitroglycerin infusion had any effects on the long-term results. In our study, in-hospital follow-up the primary end-point was postprocedural ischaemia after PCI.

Our results showed that routinely administered nitroglycerin had no effects on the occurrence of chest pain and the incidence of this event was very low. Similarly, Kurz et al. [1] observed no difference in the incidence of chest pain after PCI between the groups treated with nitroglycerin or placebo. The incidence of postprocedural chest pain was low in both groups. There are several possible causes of postprocedural pain, such as vasoconstriction, ischaemia, microembolism, activation of afferent sensory nerves or inflammatory reaction to implanted material in the case of stenting [1, 11]. Some earlier clinical trials suggested that spontaneous coronary artery vasoconstriction after PCI occurs frequently and was described as progressive vasoconstriction (defined as a loss of diameter that was reversed by intracoronary nitroglycerin) observed after PCI in the dilated and distal segments. It has been shown that coronary artery vasoconstriction after PCI is rapidly reversed by intracoronary nitroglycerin and can be prevented by the continuous administration of intravenous nitroglycerin during and after the procedure [12-15]. Mechanical stretch and ischaemia caused by balloon inflation induces vasoconstriction mediated by alpha-adrenergic receptors (mainly alpha-1 receptors), overcoming a beta-mediated dilatation [16]. Fischell et al. observed progressive vasoconstriction after PCI despite treatment with calcium blockers and aspirin.

Our study and others promote the hypothesis that chest pain after PCI may not primarily be a problem of myocardial ischaemia, but the result of procedural microembolism, coronary spasm at the site of stent deployment, or other causes. In coronary stenting, there is an alternative conceivable mechanism that includes nociceptive phenomena caused by activation of the afferent nerves along the coronary arteries after their distension by a stent or localised inflammatory reactions to implanted material.

Study limitations

There was a shortage of troponin assessment and deficiency in clopidogrel use, mainly due to the high cost of this management in 2001. The study group was relatively small and our findings need to be confirmed in a larger study.

Conclusions

Routine use of intravenous nitroglycerin after elective PCI has no effect on the short- or long-term outcome. The rate of long-term complications after elective PTCA is low, even with moderate use of stenting and abciximab infusion.

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Podawanie nitrogliceryny po przezskórnej interwencji wieńcowej nie wpływa na wczesne i odległe rezultaty leczenia – badanie prospektywne NAPI (*Nitroglycerin Administration after Percutaneous Intervention*)*

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Streszczenie

Wstęp: Nitrogliceryna z powodzeniem jest stosowana w kardiologii od ponad stu lat. Przed epoką trombolityków stosowano ją w ostrym zawale serca (MI), ze względu na udowodnione zmniejszenie śmiertelności oraz ograniczenie strefy martwicy. Nitrogliceryna zmniejsza napięcie mięśni gładkich, ograniczając w ten sposób kurcz naczyń wieńcowych, co skutkuje zwiększonym dopływem tlenu do stref niedokrwienia także poprzez kolaterale. Niektóre prace donoszą o samoistnym kurczu naczynia wieńcowego (ang. *spontaneous coronary artery vasoconstriction*), definiowanym jako odwracalny po dowieńcowym podaniu nitrogliceryny, który nierzadko występuje po przezskórnych zabiegach na naczyniach wieńcowych (PTCA). Na podstawie tego założenia powstało przypuszczenie, że dożylny wlew nitrogliceryny zainicjowany podczas zabiegu PTCA lub bezpośrednio po nim może zapobiegać zjawisku samoistnego kurczu docelowego naczynia wieńcowego. Te własności nitrogliceryny pozwalają sądzić, że jej zastosowanie po PTCA w stabilnej chorobie niedokrwiennej serca może także być korzystne. Choć korzyści z zastosowania wlewu nitrogliceryny u pacjentów po planowej angioplastyce wieńcowej (PCI) nie są jeszcze udokumentowane, procedura ta jest rutynowo wdrażana w niektórych ośrodkach. Ze względu na stale rosnącą liczbę zabiegów PCI, również w grupie chorych ze stabilną dusznicą bolesną, problem ten ma istotne znaczenie we współczesnej kardiologii.

Cel: Podwójnie zaślepione, jednoośrodkowe badanie z randomizacją NAPI – *Nitroglycerin Administration after Percutaneous Intervention* (Podawanie Nitrogliceryny po Przezskórnej Interwencji) sprawdzało skuteczność rutynowego wlewu nitrogliceryny w 1. dobie po PCI.

Metodyka: Dwustu pacjentów po zabiegu planowej PCI zostało losowo przypisanych do grupy leczonej nitrogliceryną (100 pacjentów, średni wiek 58±6 lat, wlew do 100 µg/min) lub placebo (100 pacjentów, średni wiek 57±5 lat, p=NS, NaCl 0,9%) podczas pierwszych 12 godz. po PCI. Pacjenci z ostrym MI, niestabilni hemodynamicznie w czasie PCI lub z rozpoznaną nietolerancją nitratów zostali wyłączeni z badania. Pacjenci zrandomizowani do grupy placebo mieli możliwość otrzymania nitratów na zlecenie lekarza prowadzącego. Obserwacja wewnątrzszpitalna i odległa, 24-miesięczna, była prowadzona pod kątem następujących klinicznych punktów końcowych: zgonu sercowego, zawału serca, powtórnej PCI, obecności bólu w klatce piersiowej po PCI i niestabilnej choroby wieńcowej.

Wyniki: W obserwacji wewnątrzszpitalnej nie wykazano żadnych różnic co do śmiertelności (0 *vs* 0%, p=NS), MI (0 *vs* 2%, p=NS), pointerwencyjnego bólu w klatce piersiowej (10 *vs* 8%, p=NS) ani powtórnej PCI (0 *vs* 2%, p=NS) pomiędzy grupami otrzymującymi nitroglicerynę i placebo. Podobnie, obserwacja 24-miesięczna nie wykazała istotnych statystycznie różnic pomiędzy pacjentami otrzymującymi nitroglicerynę i placebo pod względem śmiertelności (0 *vs* 0%, p=NS), MI (4 *vs* 4%, p=NS), powtórnej PCI (10 *vs* 8%, p=NS) czy CABG (0 *vs* 0% p=NS).

Wnioski: Rutynowe zastosowanie dożylnego wlewu nitrogliceryny po PCI nie ma wpływu na przebieg wewnątrzszpitalny, oceniany wystąpieniem zgonu sercowego, MI, bólu w klatce piersiowej po PCI, niestabilnej choroby wieńcowej i konieczności ponownej PCI. Również w obserwacji 24-miesięcznej nie wykazano żadnych istotnych statystycznie różnic pomiędzy grupą leczoną rutynowo wlewem nitrogliceryny w 1. dobie po PCI a grupą otrzymującą placebo. Nasze wnioski mogą mieć zatem aspekt farmakoekonomiczny, dość istotny ze względu na niemałą cenę preparatów dożylnych nitrogilceryny oraz skalę zjawiska dla całego kraju.

Słowa kluczowe: elektywna angioplastyka wieńcowa, nitraty, przezskórna angioplastyka wieńcowa

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