

# Utilisation of bivalirudin and vascular closure devices for same-day discharge after percutaneous coronary and peripheral interventions

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## Abstract

**Background:** Currently the majority of coronary and peripheral interventions are performed with an overnight stay. This increases the cost and does not reduce logistic constraints on hospital resources. We hypothesised that by combining bivalirudin with vascular closure devices we can safely discharge patients on the same day after percutaneous coronary intervention (PCI) and percutaneous transluminal angioplasty (PTA) without increasing their risk of bleeding.

**Aim:** To evaluate the safety and the feasibility of same-day discharge after PCI and PTA using bivalirudin and vascular closure devices.

**Methods:** This is a retrospective analysis of 833 consecutive patients who underwent percutaneous procedures in our centre between January 2007 and February 2010. The population was divided into interventional and diagnostic arms. All interventions were done with use of bivalirudin for anticoagulation and vascular closure devices for achieving haemostasis. Haemostasis in the diagnostic cohort was achieved with standard manual compression. The mean time of observation was 30 days. The mean age of patients was 64.3 years. The primary endpoint was any bleeding event meeting GUSTO criteria. The secondary endpoints included local vascular complications, major adverse cardiac and cerebrovascular events, time to ambulation and discharge, as well as need for overnight hospitalisation.

**Results:** In 30-day observation the primary endpoint occurred in 4.0% of patients in the interventional group and in 2.6% of patients in the diagnostic group ( $p = 0.31$ ). The frequency of local vascular complications was higher in the interventional group although it was not statistically significant (3.1% vs. 2.9%;  $p = 0.33$ ). Patients from the interventional group were ambulated sooner compared to the diagnostic group (117.5 vs. 131 min;  $p = 0.003$ ). Time to discharge was  $316.4 \pm 38.7$  min and  $214.2 \pm 23.4$  min for interventional and diagnostic procedures, respectively ( $p < 0.001$ ).

**Conclusions:** PCI and PTA in the selected group of patients, with use of bivalirudin and vascular closure devices, do not appear to have increased risk of post-procedural events when compared to diagnostic procedures, and can be done safely without the need for an overnight stay.

**Key words:** bivalirudin, vascular closure devices, same day discharge

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## INTRODUCTION

New developments in the field of cardiology and endovascular surgery, minimisation of the equipment, use of novel vascular closure devices, and modern antithrombotic therapy allow percutaneous procedures to be performed without the need

for overnight observation [1–7]. Safety of the early mobilisation and discharge after diagnostic percutaneous procedures has been tested in multiple trials over the last few years [8, 9]. Several reports have shown that shortened observation after percutaneous coronary intervention (PCI) and percutaneous

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transluminal angioplasty (PTA) in selected groups of patients does not increase the number of complications compared to an extended observation and hospitalisation [10–12]. Despite multiple studies with encouraging results this model still remains controversial and is not the standard of care. The aim of the study was to evaluate the safety and feasibility of same-day discharge after PCI and PTA with the use of bivalirudin for anticoagulation and vascular closure devices for achieving haemostasis.

### Study design. Inclusion, exclusion criteria

We analysed data of 953 consecutive patients who were admitted to San Antonio Endovascular and Heart Institute (SAEHI) between January 2007 and February 2010 in order to undergo percutaneous coronary or peripheral, diagnostic or interventional procedure. A total of 833 (87.4%) patients who met the study criteria were included into a retrospective analysis. The therapeutic (interventional) group comprised patients with significant coronary and/or peripheral artery stenosis with clinical indications for invasive treatment. In this group bivalirudin was used for anticoagulation, and vascular closure devices (VCD) were used to achieve local haemostasis.

The diagnostic group comprised patients without significant coronary and peripheral vascular disease or patients who had contraindications for percutaneous revascularisation. These patients did not require anticoagulation and haemostasis post procedure was achieved with manual compression.

Patients with ST elevation myocardial infarction, non ST elevation myocardial infarction, acute ischaemia of lower extremities, use of heparin, glycoprotein IIb/IIIa blockers or oral anticoagulants during 48 h prior to diagnostic or therapeutic intervention, or vascular access other than via the femoral artery, were excluded from the analysis.

One hundred and twenty patients were excluded from the analysis because of failure to meet the inclusion criteria or the occurrence of at least one of the exclusion criteria. Out of the 120 patients who were excluded from the registry: 12 had VCD applied after diagnostic procedure in addition to manual compression; eight interventional patients had contraindications to VCD; 16 patients received an oral anticoagulant; and 12 received low molecular weight heparin. In four cases the data contained in the medical record was incomplete and did not allow for a detailed analysis. In 68 patients the procedures were performed using radial access. A scheme of the conducted study is presented in Figure 1.

## METHODS

All procedures and angiographic studies were performed according to commonly applied standards. All procedures were conducted according to the SAEHI protocol. The decision on discharge was made after an assessment of the injection site and clinical condition of each patient, and was at the discretion of the attending physician. All discharged patients

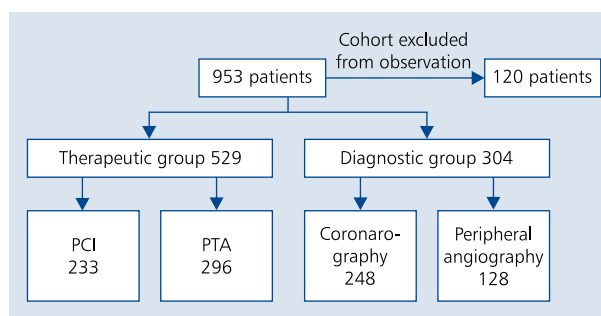


Figure 1. Scheme of the conducted study; PCI — percutaneous coronary intervention; PTA — percutaneous transluminal angioplasty

in the interventional group had a scheduled follow-up in an outpatient clinic at one, 14, and 30 days after the procedure. All diagnostic patients had scheduled follow up at 14 and 30 days post procedure. During follow-up visit each patient had an ultrasound done to assess the vascular access site, and blood was drawn for morphology and chemistry. All data was collected in an electronic database. In the event of complications and contraindications to same-day discharge, patients were admitted for observation to an inpatient service. The assessment of clinical condition, both before discharge and at follow-up was conducted by an attending physician. All access site complications were confirmed by Doppler ultrasound or computed tomography, and assessed by a vascular surgeon.

Patients who underwent interventional procedures had previously received clopidogrel at a dose of 75 mg/day, or received a single loading dose of 600 mg on the day of the procedure. Patients who required an intervention received a bolus of bivalirudin at a dose of 0.75 mg/kg, followed by a continuous infusion during the procedure of 1.75 mg/kg/h. After angioplasty the infusion of bivalirudin was stopped. All diagnostics were performed with no anticoagulation therapy. The patients discharged home were strictly advised to take aspirin at a daily dose of 81 mg life-long and clopidogrel at a daily dose of 75 mg for at least one year. The decision to prescribe other medicines, such as statins, angiotensin-converting-enzyme inhibitors, or beta-blockers, was at the discretion of the attending physician. All diagnostics were performed with no anticoagulation therapy.

### Endpoints

The primary endpoint of the study was the occurrence of any bleeding event. Bleedings were stratified by Global Strategies for Opening Occluded Coronary Arteries (GUSTO) criteria:

- severe bleeding — intracranial bleeding or severe, life-threatening bleeding, causing haemodynamic instability;
- moderate bleeding — bleeding requiring an adjunct transfusion, not causing haemodynamic disorders;

— mild bleeding — which does not meet the criteria for severe or moderate bleeding according to the GUSTO classification.

The secondary end points of the study were:

- local vascular events;
- adverse cardiac and cerebrovascular events (MACCE);
- time to ambulation;
- time to discharge;
- a necessity of overnight observation.

The endpoints were assessed by analysing patient records. Deaths were confirmed by checking the Social Security Number (SSN) in the national database and by telephone calls to the families of the patients.

### Applied definitions

Local vascular events were defined as: haematoma > 5 cm, pseudo-aneurysm, arteriovenous fistula, retroperitoneal bleeding, embolism/arterial thrombosis, infection at the arterial cannulation site, and the need for surgical intervention at the vascular access site.

Major local vascular events were defined as: retroperitoneal bleeding, embolism/arterial thrombosis, haematoma > 15 cm, pseudo-aneurysm with a diameter > 5 cm, haemodynamically significant arteriovenous fistula, and the need for surgical intervention at the vascular access site.

MACCE were defined as: death, stroke, myocardial infarction (MI), repeated revascularisation (target vessel revascularisation [TVR]), and amputation of an extremity.

Perioperative MI was defined as a threefold increase of creatine kinase isoenzyme (CK-MB) above the upper limit of the hospital reference range. Death was recognised as a death from any cause. Haematoma was defined as a blood extravasation within perivascular tissues with a minimum diameter of 5 cm. Pseudo-aneurysm was defined as a blood-filled space outside an artery having a continuous connection with an artery via a so-called “neck” of the haematoma. Arteriovenous fistula was defined as a pathological connection between an artery and a vein caused by an iatrogenic event. Arteriovenous fistula was defined as significant if it caused haemodynamic disturbances. Retroperitoneal bleeding (retroperitoneal haematoma) was defined as blood extravasation into retroperitoneal space, confirmed by computed tomography. Thrombosis/embolism in a lower extremity was defined as a partial or complete closure of a lumen of a vessel by a thrombotic/embolic material, confirmed by imaging studies. Infection at the injection site was defined as an exodermatitis and cellulitis at the vascular access site, confirmed by a physical examination. The need for a surgical intervention at the vascular access site was defined as any treatment/surgical intervention required to achieve vascular haemostasis or to manage vascular and bleeding events caused by an iatrogenic event. Bleeding events were defined according to the GUSTO clinical classification of bleedings.

Table 1. Baseline characteristics

	Therapeutic group (n = 529)	Diagnostic group (n = 304)	P
Male	316 (59.7%)	154 (50.6%)	0.01
Age	63.6 ± 11.4	66.1 ± 11.2	0.02
BMI [kg/m <sup>2</sup> ]	30.1 ± 6.1	30.3 ± 5.5	0.74
Obesity	236 (44.6%)	127 (41.8%)	0.42
Morbid obesity	54 (10.2%)	42 (8.1%)	0.11
Hyperlipidaemia	430 (81.2%)	261 (85.9%)	0.09
Hypertension	442 (83.5%)	253 (83.2%)	0.90
Diabetes	231 (43.6%)	175 (57.5%)	< 0.001
Smoker	179 (33.8%)	102 (33.5%)	0.87
LVEF [%]	55.8 ± 6.3%	56.9 ± 5.6%	0.12
ESRD	67 (12.6%)	28 (9.2%)	0.21
History of stroke	51 (9.6%)	23 (7.6%)	0.31
History of MI	103 (19.5%)	45 (14.8%)	0.08
Coronary artery disease	331 (62.6%)	117 (38.5%)	< 0.001
Peripheral artery disease	313 (59.1%)	102 (33.5%)	< 0.001
Unstable angina	94 (17.7%)	39 (12.8%)	0.06
History of amputation	27 (5.1%)	11 (3.6%)	0.32

BMI — body mass index; LVEF — left ventricular ejection fraction; ESRD — end-stage renal disease; MI — myocardial infarction

### Statistical analysis

Parametric data were presented using mean value and standard deviation, and non-parametric data as absolute value and percentage. Parametric values with a normal distribution were compared between the groups using Student's t test. The frequency of occurrence of non-parametric features in sub-groups was compared using  $\chi^2$  test with Yates and F-Cox correction.

Analyses of relationships between the studied factors and the occurrence of the primary endpoint, and the secondary endpoints, were conducted using cross-tables with an  $\chi^2$  test of dependence. The test probability at  $p < 0.05$  was considered.

Analyses of the results were conducted using the PQStatver 1.4.2.324 and GraphPadPrism 6 statistical software packages.

## RESULTS

### Baseline characteristics and procedural data

Characteristics of the study population are presented in Table 1. PCI and PTA procedural data are shown in Tables 2 and 3. Four types of VCD were used to obtain local haemostasis in the therapeutic group (Fig. 2).

### Bleeding events

During a 30-day observation, 37 (4.4%) bleeding events, classified according to the III-point GUSTO scale of bleedings, were reported in a total group of 833 analysed patients. The

**Table 2.** Percutaneous coronary intervention (PCI) — technical data

Procedural data	PCI (n = 233)
Predilatation	42
Postdilatation	193
Balloon angioplasty	39
Stent implantation	194
Intravascular ultrasound	195
Stent per procedure	1.04
Drug eluting stent	240
Bare metal stent	3

**Table 3.** Percutaneous transluminal angioplasty (PTA) — technical data

Procedural data	PTA (n = 296)
Number of treated arteries	477
Predilatation	19
Postdilatation	43
Balloon angioplasty	370
PTA with stent	99
Endarterectomy	23
Intravascular ultrasound	8
Number of treated arteries per procedure	1.3
Antegrade stick	121

primary end point (i.e. the occurrence of any bleeding event) occurred in 20 (4.0%) patients in the therapeutic group and in eight (2.6%) patients in the diagnostic group ( $p = 0.31$ ; Fig. 3).

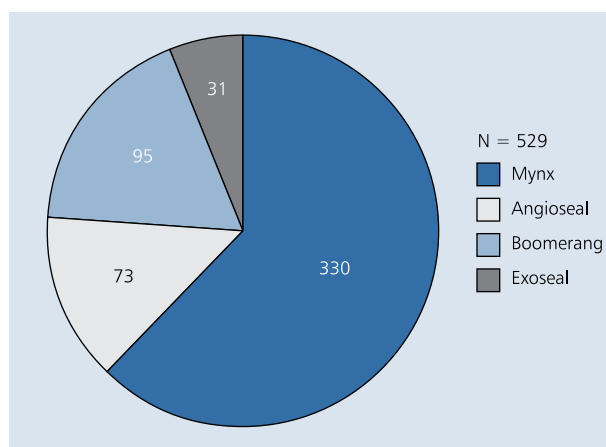
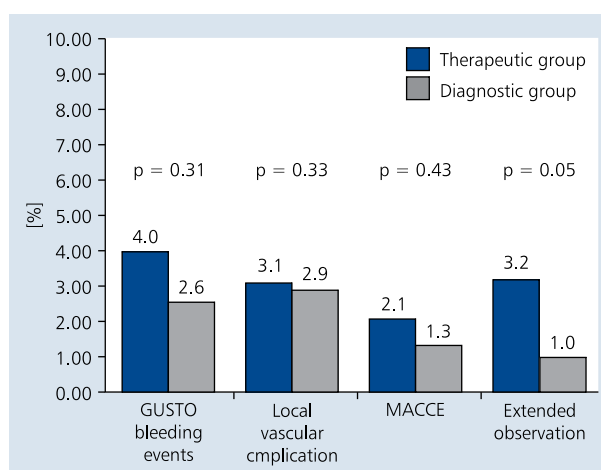
There were no severe bleeding episodes in the therapeutic or the diagnostic group. In the therapeutic group, two (0.4%) patients had moderate bleeding and required an adjunct blood transfusion. All other bleeding events in both groups were classified as mild and did not require any additional intervention (Table 4).

#### Local vascular events

During 30-day observation, 26 (3.1%) local vascular events occurred in the study population. A summary of local vascular events in both diagnostic and therapeutic groups is presented in Table 5. Major local vascular events were observed in five (0.9%) patients in the therapeutic group and in one (0.3%) patient in the diagnostic group ( $p = 0.29$ ; Table 4).

#### Major adverse cardiac and cerebrovascular events

During the 30-day period post-procedure, 15 (1.8%) MACCE were observed. MACCE occurred in 11 (2.1%) patients in the

**Figure 2.** Types of vascular closure devices used in the study**Figure 3.** Thirty-day observation. Primary and secondary endpoints; MACCE — death, stroke, myocardial infarction, repeated revascularisation (target vessel revascularisation), amputation of an extremity

therapeutic group, compared to four (1.3%) patients in the diagnostic group (Fig. 3). The summary of MACCE occurrences is presented in Table 7.

#### Extended observation

Seventeen (3.2%) patients from the therapeutic arm required overnight stay, compared to three (1.0%) patients after diagnostic procedures. No statistically significant difference was observed between the two groups (Fig. 3).

#### Time to mobilisation and discharge of the patients

Patients in the therapeutic group were significantly sooner mobilised compared to diagnostic patients (Table 8). The average time to discharge of the patients belonging to the diagnostic group was significantly shorter compared to the

**Table 4.** Thirty-day observation. Bleeding complications according to GUSTO criteria

	Therapeutic group (n = 529)	Diagnostic group (n = 304)	P
Severe bleeding	0	0	NS
Moderate bleeding	2 (0.4%)	0	0.20
Mild bleeding	19 (3.6%)	8 (2.6%)	0.45

**Table 5.** Thirty-day observation. Local vascular events

	Therapeutic group (n = 529)	Diagnostic group (n = 304)	P
Haematoma ≥ 5 cm	10 (1.9%)	4 (1.3%)	0.53
Pseudoaneurysm	4 (0.7%)	1 (0.3%)	0.44
Retroperitoneal bleeding	2 (0.4%)	0	0.28
Surgical intervention	0	0	NS
Arteriovenous fistula	0	2 (0.7%)	0.06
Infection at the arterial cannulation site	1 (0.2%)	2 (0.7%)	0.27

**Table 6.** Thirty-day observation. Major local vascular events

	Therapeutic group (n = 529)	Diagnostic group (n = 304)	P
Haematoma ≥ 15 cm	2 (0.4%)	1 (0.3%)	0.90
Pseudoaneurysm > 5 cm	1 (0.2%)	0	0.44
Retroperitoneal bleeding	2 (0.4%)	0	0.28
Surgical intervention	0	0	NS

**Table 7.** Thirty-day observation. Major adverse cardiac and cerebrovascular events

	Therapeutic group (n = 529)	Diagnostic group (n = 304)	P
Repeated revascularisation*	4 (0.7%)	–	NA
Stroke	1 (0.2%)	1 (0.3%)	0.69
Myocardial Infarction	3 (0.6%)	1 (0.3%)	0.63
Extremity amputation	1 (0.2%)	2 (0.6%)	0.27
Death	2 (0.4%)	0	0.28

\*Target vessel revascularisation; NA — not available

patients belonging to the therapeutic group and equalled 214.2 ± 23.4 min and 316.4 ± 38.7 min, respectively (p < 0.001; Table 8).

**Table 8.** Time to mobilisation and discharge of the patients

	Therapeutic group (n = 529)	Diagnostic group (n = 304)	P
Time to mobilisation [min] mean; median	117.5 ± 31.4; 125.5	131 ± 16.9; 147.0	0.003
Time to discharge [min] mean; median	316.4 ± 38.7; 348	214.2 ± 23.4; 229	< 0.001

## DISCUSSION

This is one of the largest single-centre registries on percutaneous interventions with use of bivalirudin and VCD to facilitate the discharge process. There were no major differences between the two groups in regard to baseline characteristics, except that diabetes was more prevalent in the diagnostic cohort, and history of coronary artery disease/peripheral artery disease was more frequent in the therapeutic arm. A large percentage of patients in the diagnostic group was excluded from intervention due to the advanced and multivascular nature of their lesions in coronary (18%) and peripheral (13%) arteries and required surgical treatment.

Currently the risk of major local bleeding events in patients undergoing cardiac catheterisation or peripheral arterial angiography is low and does not exceed 1% [7]. Recent advances in technology, including smaller size of diagnostic catheters, no need for anticoagulation, and short duration of the procedure substantially minimised the risk associated with catheterisation. Interventions, on the other hand, usually carry higher risk that is often dependent on the patient's individual risk profile. Recent scientific reports suggest that in the moderate-risk group severe local vascular and bleeding events occur with a frequency of 1–3% [13–15]. Patients with multiple risk factors such as advanced age, peripheral vascular disease, liver disease, and coagulation abnormalities, immunosuppressed patients, and those whose endovascular interventions are performed as an emergency carry the highest risk of local vascular and bleeding events. In this population the frequency of severe local bleeding events exceeds 3% [16]. In our study the majority of patients in the therapeutic group were at intermediate to high risk of local vascular complications, while the patients who underwent diagnostic procedures were mostly at intermediate risk. The number of bleeding events in the studied groups is comparable to the data available in the literature [8–12].

The primary endpoint of the study was the occurrence of any bleeding event, and later stratified by GUSTO criteria. Analysis of the results did not reveal any difference in the incidence of bleeding events between the therapeutic group and the diagnostic group (4.0% vs. 2.6%, respectively). It is noteworthy that no severe bleeding events occurred, neither in the therapeutic nor in the diagnostic group, while moder-

ate bleeding requiring an adjunct blood transfusion occurred only in two patients who underwent therapeutic procedures.

In the therapeutic group 0.9% out of 4.0% of complications were classified as major local vascular events, while in the diagnostic group the percentage of major local vascular events was lower (0.3%) but statistically not significant. The risk of severe local complications in the diagnostic group in this study was concordant with data presented in other reports. It is particularly consistent with the analysis presented by Doyle et al. [17] who analysed 1005 patients after diagnostic cardiac catheterisation.

The authors observed a low rate of local bleeding events (0.1% major events and 3.3% minor events). Available data suggest that bleeding events following endovascular procedures are quite common and their frequency depends on the type of adjuvant anticoagulant therapy and the characteristics of the population [18–23]. As demonstrated in numerous studies the occurrence of bleeding complications is associated with a higher risk of adverse events such as MI, stroke, stent thrombosis, and death, both in short- and long-term observation [24]. The HORIZONS-AMI and EUROMAX trials showed that bivalirudin is superior to heparin plus glycoprotein IIb/IIIa in reducing net adverse clinical events in patients with acute MI undergoing primary PCI, at the cost of increased rate of acute stent thrombosis [19, 25]. In the BRIGHT trial of patients with acute MI undergoing PCI the authors observed that bivalirudin alone was superior to both heparin monotherapy and heparin plus tirofiban in reducing the primary composite endpoint of death, re-infarction, ischaemia-driven TVR, stroke, and any bleeding (8.8% vs. 13.2% vs. 17.0%) at 30-day and one-year observation (12.8% vs. 16.5% vs. 20.5%). The authors also showed that bivalirudin reduced major and minor bleeding events (4.1% vs. 7.5% vs. 12.3%) and thrombocytopenia (0.1% vs. 0.7% vs. 1.1%) [26]. They observed similar rates of acute and subacute stent thrombosis in the compared groups (0.6% vs. 0.9% vs. 0.7%) [26]. Quite different results were observed by HEAT-PPCI investigators [27]. This prospective, randomised trial showed an increased rate of stent thrombosis after bivalirudin infusion when compared to unfractionated heparin (UFH) (3.4% vs. 0.9%), respectively. Major and minor bleeding did not differ between both groups [27]. In our cohort we observed in-stent thrombosis in two patients. Both patients were in the interventional arm requiring bivalirudin during revascularisation; however, events occurred after discharge and in both cases double antiplatelet therapy was discontinued before stent thrombosis occurred. We do not have a UFH arm with which to make any direct comparisons, but the number of stent thromboses in our study was very low compared to other reports, and together with the low MACE suggests that use of bivalirudin is very safe in percutaneous revascularisation. Our results support favourable outcomes of the HORIZONS, EURMAX, BRIGHT trials. Due to possible impact of bleeding events on long-term mortality, further analysis should be conducted to assess mortality after 30 days.

In the therapeutic arm VCDs were used in order to achieve local haemostasis. Data on the superiority of VCD over manual compression in terms of safety and operational effectiveness is ambiguous. However, the fact that the use of closure devices significantly decreases the time needed for the achievement of haemostasis and mobilisation of patients who underwent endovascular interventions via femoral artery access remains indisputable. Thus, the patients of the therapeutic group were mobilised earlier post-procedure (mean 117.5 min) compared to the diagnostic group (mean 131 min) where local haemostasis was achieved by manual compression. Despite earlier ambulation patients in the therapeutic group remained in the clinic significantly longer than the patients in the diagnostic group (316.4 min and 214.2 min, respectively). This is due to the time required to discuss the performed procedures and communicate appropriate recommendations regarding both medication and lifestyle. Moreover, in the therapeutic group a greater number of patients (3.2%) required an extended in-patient observation.

Several reports demonstrated that early ambulation and early discharge of patients after endovascular procedures with use of VCD for closure of arteriotomy site does not increase the risk of complications compared to patients staying overnight for observation [28, 29].

Bertrand et al. [9] analysed 1005 patients after coronary angioplasty procedures in a study comparing same-day discharge with overnight hospitalisation. The incidence of severe bleeding in both groups was small and equalled 0.8% in the group of patients discharged on the day of the procedure and 0.2% in the group of hospitalised patients. In the present study no severe bleeding events were observed. Also, the number of patients requiring overnight stay in our study appears favourable when compared to other published reports. In Bertrand's analysis, 12% of patients randomised to an early discharge required an extended observation compared to 3.2% in our cohort. Heyde et al. [10] reported as many as 19% of the patients to be disqualified from discharge on the day of the procedure after PCI. The difference between our study and two other studies is in the agent used for anticoagulation. Both analyses by Bertrand et al. [9] and Heyde et al. [10] used mainly heparin for anticoagulation instead of bivalirudin.

The number of cardiovascular and cerebral events observed by Heyde et al. [10] and Bertrand et al. [9] in groups of patients discharged on the day of the procedure is very similar to the data presented in our study. However, in the present study a lower number of local complications, both in the therapeutic and diagnostic group (3.1% vs. 2.9%, respectively), were observed.

### *Limitations of the study*

Because of the observational retrospective nature of this study, all the analyses are only hypothesis-generating and should be confirmed in prospective trials. The number of patients in both

groups is relatively small. Also, due to the non-randomised nature of this study, there were minor differences between the two cohorts in baseline characteristics as age, gender, history of diabetes, and artery disease that could influence bleeding risk. Further studies with longer follow-up should be conducted.

## CONCLUSIONS

The perioperative protocol for percutaneous coronary and peripheral interventions applied in the present study was associated with a low risk of local and general complications. The incidence of complications did not differ between groups of patients subjected to diagnostic and therapeutic procedures. The combination of modern anticoagulation therapy and VCD in the selected group of patients enables early and safe mobilisation of patients undergoing invasive therapeutic procedures with no need for overnight hospitalisation.

**Conflict of interest:** none declared

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# Zastosowanie biwalirudyny i okluderów dostępu naczyniowego w zabiegach przezskórnej angioplastyki naczyń wieńcowych i obwodowych prowadzonych w trybie ambulatoryjnym

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## Streszczenie

**Wstęp i cel:** Celem badania była ocena bezpieczeństwa i skuteczności stosowania biwalirudyny w połączeniu z urządzeniami do zamykania miejsca kaniulacji tętnicy udowej w grupie pacjentów po zabiegach przezskórnej interwencji wieńcowej (PCI) oraz przezskórnej angioplastyki transluminalnej (PTA) prowadzonych w trybie ambulatoryjnym.

**Metody:** Retrospektywną analizą objęto 833 pacjentów, u których przeprowadzono zabiegi endowaskularne diagnostyczne lub terapeutyczne. Badaną populację podzielono na dwie grupy: interwencyjną i diagnostyczną. W grupie interwencyjnej hemostazę uzyskiwano poprzez zastosowanie urządzeń zamykających miejsce wkłucia, w grupie diagnostycznej natomiast przy użyciu kompresji manualnej. W grupie terapeutycznej stosowano biwalirudynę jako wspomagającą terapię przeciwkrzepliwą. Zabiegi diagnostyczne przeprowadzono bez antykoagulacji. Okres obserwacji wynosił 30 dni, a średni wiek populacji — 64,3 roku. Pierwszorzędowym punktem końcowym badania było wystąpienie powikłań krwotocznych klasyfikowanych wg skali GUSTO. Do drugorzędowych punktów końcowych należały: miejscowe powikłania naczyniowe, poważne zdarzenia sercowo-naczyniowe, czas do uruchomienia i wypisania oraz konieczność obserwacji całodobowej.

**Wyniki:** Pierwszorzędowy punkt końcowy wystąpił u 21 (4,0%) pacjentów z grupy interwencyjnej oraz u 8 (2,6%) pacjentów z grupy diagnostycznej ( $p = \text{NS}$ ). Częstość występowania miejscowych powikłań naczyniowo-krwotocznych była nieistotnie wyższa w grupie terapeutycznej (3,1% vs. 2,9%;  $p = \text{NS}$ ). W grupie terapeutycznej pacjentów uruchamiano istotnie szybciej w porównaniu z chorymi z grupy diagnostycznej (117,5 vs. 131 min;  $p < 0,01$ ).

**Wnioski:** Zastosowanie biwalirudyny i urządzeń do zamykania miejsca kaniulacji tętnicy udowej w trakcie przeprowadzania PCI oraz PTA nie zwiększa ryzyka powikłań krwotocznych w porównaniu z zabiegami diagnostycznymi prowadzonymi bez antykoagulacji, a także umożliwia przeprowadzanie zabiegów endowaskularnych w trybie ambulatoryjnym.

**Słowa kluczowe:** biwalirudyna, urządzenia zamykające miejsce kaniulacji tętnicy udowej

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