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Janine Dörffler-Melly, MD, PhD
Felix Mahler, MD
Dai-Do Do, MD
Jürgen Triller, MD
Iris Baumgartner, MD

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**Abbreviations:**
ASA = acetylsalicylic acid
VKA = vitamin K antagonists

[1] From the Swiss Cardiovascular Center, Division of Angiology (J.D., F.M., D.D.D., I.B.), and Department of Diagnostic and Interventional Radiology (J.T.), University Hospital of Berne, Inselspital, Freiburgstrasse 4, CH-3010 Bern, Switzerland. Received September 3, 2004; revision requested November 4; revision received January 10, 2005; accepted February 1. Supported by a grant from Centocor and Eli Lilly Switzerland. **Address correspondence to** I.B. (e-mail: *Iris.Baumgartner@insel.ch*).

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**Author contributions:**
Guarantor of integrity of entire study, I.B.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, J.D.; clinical studies, all authors; statistical analysis, J.D.; and manuscript editing, J.D., D.D.D., I.B.



# Adjunctive Abciximab Improves Patency and Functional Outcome in Endovascular Treatment of Femoropopliteal Occlusions: Initial Experience[1]

**PURPOSE:** To prospectively evaluate the safety and effectiveness of adjunctive administration of abciximab observed within 30 days and at 6 months after randomization in patients undergoing endovascular revascularization of long-segment femoropopliteal occlusions.

**MATERIALS AND METHODS:** The study was approved by the local ethical committee, and patients gave written informed consent. In a prospective, double-blind, placebo-controlled design, patients undergoing percutaneous treatment for long-segment (>5 cm) femoropopliteal occlusions were randomly assigned to receive abciximab or a placebo; all patients also received standard-dose heparin. Effectiveness and safety analyses were based on an intention-to-treat approach. Patency was calculated according to life-table analysis, and *P* values were derived from the log-rank statistic. The *P* values for dichotomous safety end points were calculated with the Fisher exact test. Odds ratios were calculated for subgroup analyses. Logistic regression modeling was used for analysis of the safety bleeding data.

**RESULTS:** A total of 98 patients (103 limbs) were included: 47 patients received abciximab and 51 received a placebo. Patency with abciximab versus placebo was 95.7% versus 80.4% (relative risk, 0.21; 95% confidence interval: 0.05, 0.96; $P = .02$) at 30 days and was 61.7% versus 41.2% (relative risk, 0.57; 95% confidence interval: 0.32, 1.01; $P = .03$), coupled with a better clinical outcome according to the Rutherford score, at the end of follow-up ($P = .03$). Risk of major bleeding was not significantly increased, while access-site bleeding was significantly higher among patients receiving abciximab (odds ratio, 2.9; 95% confidence interval: 1.04, 8.2; $P = .04$).

**CONCLUSION:** The data show that adjunctive administration of abciximab has a favorable effect on patency and clinical outcome in patients undergoing complex femoropopliteal catheter interventions not hampered by serious bleeding. Treatment effect of abciximab observed at 30 days was maintained at 6-month follow-up.


Peripheral catheter interventions such as angioplasty, stent implantation, or thromboembolectomy inevitably produce damage to the endothelium and, to varying degrees, the underlying arterial wall. Problematic is an often extensive degree of vessel wall damage coupled with low shear stress and poor infrapopliteal outflow (1–3). In particular, complex peripheral interventions such as infrapopliteal angioplasty, revascularization of long-segment superficial femoral artery and popliteal artery occlusions, or simultaneous treatment of femoropopliteal and infrapopliteal disease have a low success rate (4,5). The exposed surfaces are highly thrombogenic and contribute to acute complications such as early reocclusion, distal embolization, and neointimal proliferation (1,2).

Local thrombotic occlusion in this setting is initiated by platelet adhesion, activation, and aggregation, which all together trigger activation of the coagulation system (6). The standard therapy that is commonly used to prevent thrombosis is a combination of heparin and platelet inhibitors (7,8). Because platelets can be activated by means of multiple pathways, the administration of a single antiplatelet drug often does not fully reduce platelet aggregation. In fact, conventional antiplatelet strategies with acetylsalicylic acid (ASA), clopidogrel, and dipyridamole—even when combined with heparin—are often insufficiently potent to prevent reocclusion in complex interventions. Risk is particularly high in patients undergoing recanalization of long-segment femoropopliteal occlusions (9–13); accordingly, new strategies are required in this high-risk group of patients. Abciximab, a highly potent antiplatelet agent that inhibits the binding of fibrinogen to the glycoprotein IIb/IIIa receptor on the platelet surface has been shown to reduce platelet-mediated thrombotic complications and markedly attenuate the risk of acute ischemic events in patients undergoing percutaneous coronary interventions (14), without increased risk of hemorrhage (15,16). To our knowledge, it has not yet been evaluated whether the clinical benefit and safety of adjunctive administration of abciximab can be translated to patients undergoing peripheral catheter interventions in a prospective randomized trial.

Thus, the purpose of our study was to prospectively evaluate the safety and effectiveness of adjunctive administration of abciximab in patients undergoing endovascular revascularization of long-segment femoropopliteal occlusions, as observed within 30 days and at 6 months after randomization.

## MATERIALS AND METHODS

### Study Population

This study was a prospective, randomized, double-blind, placebo-controlled, single-center, investigator-initiated trial performed to compare the safety and effectiveness of abciximab (ReoPro; Eli Lilly/Centocor, Vernier, Switzerland) versus placebo in patients undergoing endovascular revascularization of long-segment femoropopliteal occlusions. Eli Lilly/Centocor Europe provided blinded study medication. Authors had control of data and information submitted for publication. Patients were eligible for randomization if they were older than 18 years and had an occlusion of more than 5 cm in the native femoropopliteal artery (this includes the trifurcation) (TransAtlantic Inter-Society Consensus type D lesion) (7). Exclusion criteria were peripheral revascularization performed within the previous month, cerebrovascular event within the previous 2 years, intracranial neoplasm, aneurysm, arteriovenous malformation, vasculitis, uncontrolled arterial hypertension with a systolic pressure of more than 200 mm Hg or a diastolic blood pressure of more than 110 mm Hg despite antihypertensive treatment, known hemorrhagic diathesis, active bleeding, major surgery, gastrointestinal bleeding, or genitourinary bleeding within the previous 6 weeks.

The protocol was approved by the local ethical committee of Berne, Switzerland. All patients gave their written informed consent to participate in this study.

### Study Protocol

Patients were randomly assigned in a double-blind fashion by means of closed envelopes to receive abciximab or placebo before the intervention; this process emphasized concealment of allocation. Definitive study randomization was accomplished during the procedure after successful guidewire passage of the occlusion. Patients were started with 100 mg ASA at least 1 day before the endovascular procedure. A standard dose of 5000 IU heparin (Roche, Basel, Switzerland) was administered with the introduction of the arterial sheath, and half a standard dose (2500 IU heparin) was administered again after 2 hours if the intervention was still ongoing. A 4-F introducer was inserted into the common femoral vein to draw venous blood samples for laboratory examination.

The investigators were free to choose the details of study design and performance. Therefore, there was no conflict of interest. Catheter interventions were performed by four different study operators (I.B., F.M., D.D.D., J.T.) who had between 8 and 30 years of experience in percutaneous peripheral artery interventions. Interventions were performed at the discretion of the operator, including balloon angioplasty or, in cases of subacute thrombosis, catheter thromboembolectomy (6–8-F sheath [Argon Medical, Munster, Germany]) and/or local catheter thrombolysis (microporous balloon catheter [Schneider, Solothurn, Switzerland], 20 000 IU urokinase [Ukidan; Boehringer, Ingelheim, Germany] per centimeter of thrombus length) as described (17).

For those patients receiving abciximab, a bolus of 0.25 mg per kilogram body weight was administered after wire passage of the occlusion and was followed by an infusion of 0.125 μg per kilogram per minute up to a maximum dosage of 10 μg per minute for 12 hours. The control group received a placebo in a preparation that was indistinguishable from the active study drug.

After completion of the procedure, therapy with intravenously administered heparin (up to a maximum dose of 10 IU per kilogram body weight per hour) was allowed to be initiated 1 hour after removal of the sheath at the discretion of the operator. Specific guidelines for the site of vascular access were early removal of arterial sheaths, compression of the femoral access site for at least 20 minutes to achieve hemostasis, strict bed rest and immobilization for a minimum of 12 hours, and wearing of a compression bandage for 16–20 hours. Secondary prevention was performed with administration of ASA (100 mg daily) started before the intervention or vitamin K antagonists (VKA) (target international normalized ratio of 2–3) in those patients who had cardial or other medical indications, such as previous venous thromboembolism, at the discretion of the operator. ASA was not recommended for use together with oral anticoagulation.

### Study End Points

The primary effectiveness outcome parameter was patency of the treated femoropopliteal target lesion within 30 days after randomization. Secondary effectiveness outcomes were patency at 24 hours and at 3 and 6 months, as well as clinical outcome based on the Rutherford clinical classification (18). Bleeding events were classified as major or minor according to the criteria used by the Thrombolysis in Myocardial Infarction Study Group (19), for which a decrease in hemoglobin of more than 5 g/dL was defined as major bleeding and a decrease of 3–5 g/dL was defined as minor bleeding. A platelet count of less than 100 000/μL was classified as a mild adverse event, and a platelet count of less than 50 000/μL was classified as a serious adverse event that indicated a premature termination of the study drug. Algorithms were provided for the management of uncontrolled bleeding, peripheral bypass surgery, and thrombocytopenia, whereas red blood cell transfusion was recommended to be

**TABLE 1**
**Clinical Classification according to the Rutherford Score**

| Score and Classification | Description |
|---|---|
| 3, Markedly improved | Symptoms gone or markedly improved; ABI increased to more than 0.90 |
| 2, Moderately improved | Still symptomatic but at least a single category improvement; ABI increased by more than 0.10 but not normalized |
| 1, Minimally improved | Greater than 0.10 increase in ABI but no categorical improvement, or vice versa (ie, upward categorical shift without ABI increase of more than 0.10) |
| 0, No change | No categorical shift and less than 0.10 change in ABI |
| −1, Mildly worse | No categorical shift but ABI decreased more than 0.10, or downward categorical shift with ABI decrease less than 0.10 |
| −2, Moderately worse | One category worse or unexpected minor amputation |
| −3, Markedly worse | More than one category worse or unexpected major amputation |

Source.—Reference 18.
Note.—The Rutherford score as reported allows classification of peripheral arterial disease according to symptoms and hemodynamic findings. ABI = ankle-brachial index.

**TABLE 2**
**Clinical and Demographic Characteristics of Patients**

| Characteristic | Abciximab Group ($n$ = 47) | Placebo Group ($n$ = 51) |
|---|---|---|
| Male sex | 21 (45) | 24 (47) |
| Age (y)* | 71 ± 11 | 71 ± 10 |
| Hypertension | 30 (64) | 30 (59) |
| Diabetes mellitus | 11 (23) | 11 (22) |
| Smoker | 23 (49) | 22 (43) |
| Renal insufficiency† | 14 (30) | 15 (29) |
| Critical limb ischemia | 14 (30) | 17 (33) |
| Acute-on-chronic disease | 31 (66) | 26 (51) |
| Length of occlusion (cm)* | 10.3 ± 3.1 | 10.9 ± 3.7 |

Note.—Except where indicated, data are numbers of patients, and data in parentheses are percentages. There were no statistically significant differences between the groups.
* Data are mean ± standard deviation.
† Serum creatinine level greater than 115 μmol/L.

administered according to the clinical guidelines of the American College of Physicians (20). Hemoglobin was measured before and 12–20 hours after randomization, and platelet counts were obtained before and at 4 hours and 12–20 hours after randomization.

The immediate angiographic result was based on angiography performed at the end of intervention and bolus infusion of the study drug. Technical success was defined as a less than 30% residual stenosis according to visual estimation after angioplasty. Patency at 24 hours and at 1, 3, and 6 months was documented by means of color-coded duplex sonography. Previously described diagnostic criteria were used for sonographic assessment. In brief, three categories were separated according to the intra-to-prestenotic peak systolic velocity index, or PSVI, as follows: less than 50% diameter reduction (PSVI $< 2.4$), 50% or more diameter reduction (PSVI $\geq 2.4$), and complete occlusion (21,22). Duplex sonographic assessment was performed by two blinded technicians who both had at least 4 years of experience with the technique. Noninvasive hemodynamic assessment was based on measurement of the ankle-brachial index. Symptoms and need for secondary interventions, including amputations, were recorded. Clinical outcome of the leg at the end of the follow-up period was assessed by using the Rutherford score, which integrated hemodynamic and clinical changes, as shown in Table 1 (18).

### Statistical Analysis

Sample size was determined from the assumption that a difference in primary patency rate of 15% (primary end point) between the study drug and the placebo would be clinically relevant at an expected standard deviation of 25–30. To have the possibility of detecting such a difference at the probability level of $\alpha = 5\%$ with a power of 80% by using a Fisher two-sided exact test, the number of patients to be treated per group was calculated as 51. Demographic data in terms of patient characteristics were analyzed by using a $\chi^2$ test for the dichotomous variables and a $t$ test for the continuous variables. Treatment characteristics of the two groups were compared by using $\chi^2$ tests. The differences among patients with regard to effectiveness and bleeding were examined according to an intention-to-treat analysis. Primary patency for reocclusion and/or restenosis of more than 50% was calculated according to life-table analysis. The data were collected at the fixed and historically acceptable time intervals of 1, 30, 90, and 180 days. The $P$ values for effectiveness were derived from the log-rank statistic; a $P$ value of less than .05 was defined as denoting a statistically significant difference. In addition, hazard ratios for patency were calculated by using proportional hazards, while the $P$ values for dichotomous safety end points were calculated with the Fisher exact test.

A fixed effects model with Cochrane software (RevMan Analyses 1.02; The Cochrane Collaboration, Oxford, England) was applied to find an association between the effectiveness of abciximab treatment at the end of follow-up and subgroups for diabetes mellitus, acute-on-chronic or chronic occlusion, and postprocedural treatment with ASA or VKA. The $\chi^2$ statistic was used to analyze frequency observations of the Rutherford score. Bleeding data were analyzed by using a logistic regression model with the following explanatory variables: abciximab, age, sex, sheath size, renal insufficiency, and high dose of heparin. The choice of these factors was based on historical data and not on statistical tests.

## RESULTS

A total of 98 patients, 45 men and 53 women (103 limbs), were enrolled between February 15, 1999, and October 15, 2001; 47 patients (50 limbs) were randomized to the active treatment (abciximab) group and 51 patients (53 limbs) were randomized to the placebo group. The technical success rate was 100%. No patients in the abciximab group and three patients in the placebo group dropped out of the study. Patients' clinical characteristics are listed in Table 2. There were no significant differences in baseline characteristics between patients in the abciximab group and those in the placebo group. The types of interven-

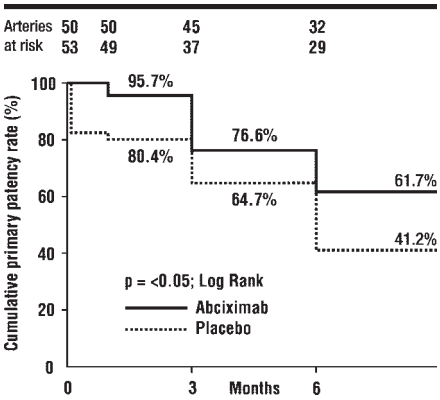



**Figure 1.** Graph of life-table analysis of primary patency rates for restenosis or reocclusion (intention-to-treat analysis) shows a significantly higher patency rate in the abciximab group compared with that in the placebo group in complex femoropopliteal interventions.

**TABLE 3**
**Comparison of Treatment Characteristics**

| Treatment* | Abciximab Group ($n$ = 47) | Placebo Group ($n$ = 51) | $P$ Value† |
|---|---|---|---|
| PTA | 15 (32) | 26 (51) | NS |
| PTA and stent placement | 12 (26) | 11 (22) | NS |
| PTA, aspiration, and lysis‡ | 22 (47) | 17 (33) | NS |
| Sheath size > 7 F | 23 (49) | 16 (22) | NS |
| 15 000–20 000 IU heparin per 24 h | 15 (32) | 18 (35) | .44 |
| Postprocedural VKA | 15 (32) | 6 (12) | .02 |
| Postprocedural ASA | 32 (68) | 45 (88) | .02 |

Note.—Data in parentheses are percentages. A majority of patients were treated with ASA throughout the follow-up period.
* PTA = percutaneous transluminal angioplasty.
† NS = not significant.
‡ Two patients in the abciximab group and three in the placebo group were treated by means of local administration of urokinase.

**TABLE 4**
**Patency Rates and Relative Risk after Endovascular Treatment**

| End Point | Patency: Abciximab Group ($n$ = 47)* | Patency: Placebo Group ($n$ = 51)* | Relative Risk† | $P$ Value |
|---|---|---|---|---|
| Primary (1 mo) | 45 (95.7) | 41 (80.4) | 0.21 (0.05, 0.96) | .02 |
| Secondary | | | | |
| 24 h | 46 (97.9) | 42 (82.4) | 0.12 (0.02, 0.95) | .01 |
| 3 mo | 36 (76.6) | 33 (64.7) | 0.59 (0.28, 1.25) | .13 |
| 6 mo | 29 (61.7) | 21 (41.2) | 0.57 (0.32, 1.02) | .03 |

* Data in parentheses are percentages.
† Data in parentheses are 95% confidence intervals.

**TABLE 5**
**Bleeding Risk**

| Risk Factor | Odds Ratio | 95% Confidence Interval | $P$ Value* |
|---|---|---|---|
| Abciximab treatment | 2.92 | 1.04, 8.18 | .04 |
| Age > 60 y | 0.96 | 0.91, 1.01 | NS |
| Male sex | 0.63 | 0.22, 1.79 | NS |
| Sheath size < 7 F | 0.87 | 0.57, 1.33 | NS |
| No renal failure† | 0.63 | 0.18, 2.29 | NS |
| Standard dose of heparin | 1.52 | 0.44, 5.24 | NS |

Note.—Treatment with abciximab was the only risk factor for bleeding events 24 hours after endovascular treatment.
* NS = not significant.
† Serum creatinine level less than 115 μmol/L.

tional treatment performed in each group are shown in Table 3. Treatment with angioplasty alone was used more often in the placebo group, whereas a sheath size larger than 7 F was used more often in the abciximab group. Postinterventional medication with VKA was prescribed significantly more often in the abciximab group, whereas ASA was prescribed more often in the placebo group ($P$ = .02). The ankle-brachial index prior to the intervention was 0.52 ± 0.15 (standard deviation) in both groups. Primary clinical success was achieved in all patients, which is expressed as a substantial immediate postprocedural increase in the ankle-brachial index (0.38 ± 0.17 in the abciximab group, 0.31 ± 0.22 in the placebo group; not a significant difference).

## Effectiveness Analyses

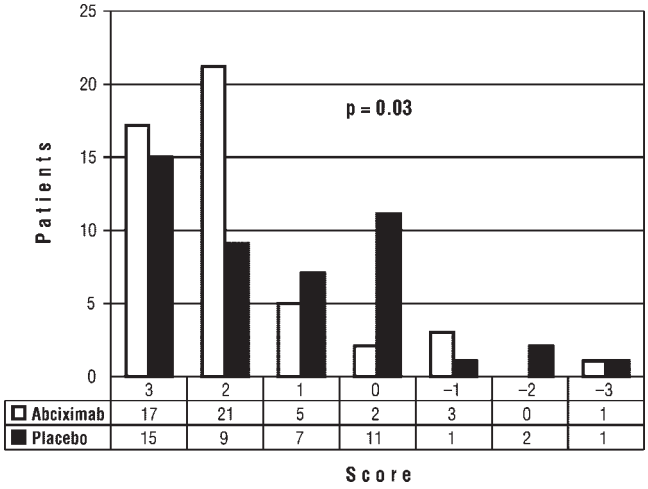
Primary patency rates and relative risk ratios with 95% confidence intervals, as well as the $P$ values obtained with the log-rank test, are shown in Table 4. The life-table analysis of primary patency rates according to treatment assignment is shown in Figure 1. Primary cumulative patency rates were 95.7% versus 80.6% ($P$ = .02) at 1 month and 61.7% versus 41.2% ($P$ = .03) at 6 months in the abciximab group and placebo group, respectively. Treatment effect of abciximab observed at 30 days was maintained at 6-month follow-up. Mean follow-up time was 153 days ± 40 and 124 days ± 65 in the abciximab group and placebo group, respectively.

Clinical outcome of the leg according to the Rutherford score was significantly better in the abciximab group than in the placebo group at the end of the follow-up period ($P$ = .03) (Fig 2).

Age, sex, pre- and postinterventional thrombocyte counts, diabetes mellitus, serum creatinine level, chronic versus acute-on-chronic femoropopliteal occlusion, and clinical stage at baseline did not significantly affect the calculated patency rates. A positive association for the effect of abciximab, however, was found in patients without compared with patients with diabetes mellitus, in patients treated with postinterventional ASA compared with those treated with VKA, and in patients treated for chronic disease compared with those treated for acute-on-chronic disease (Fig 3).

## Safety Analysis

Two patients died; one patient in the placebo group had a stroke within 6 months after the procedure, and one patient in the abciximab group died of




| | 3 | 2 | 1 | 0 | −1 | −2 | −3 |
|---|---|---|---|---|---|---|---|
| Abciximab | 17 | 21 | 5 | 2 | 3 | 0 | 1 |
| Placebo | 15 | 9 | 7 | 11 | 1 | 2 | 1 |

**Figure 2.** Graph of clinical classification, including hemodynamic changes, at the end of follow-up according to the Rutherford score (scale of 3 to −3) in patients in the abciximab group compared with those in the placebo group. *P* value was obtained with the $\chi^2$ test.

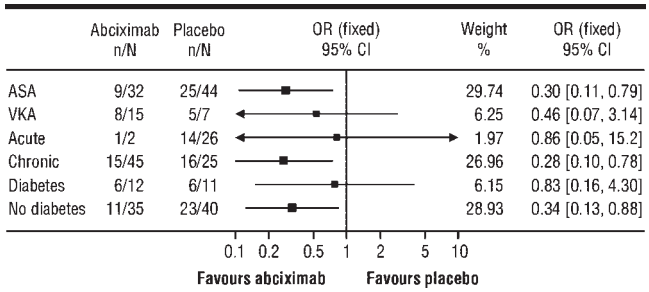



**Figure 3.** Graph of the fixed odds ratios *(OR)* and 95% confidence intervals *(95%CI)* at the end of follow-up (ie, either when the end point was reached or at the end of the 6-month observation time if no end point was reached) implies a favorable association between abciximab treatment and patients without diabetes, patients treated with ASA, and patients treated for chronic occlusions. *n/N* = number of events/number of participants per group.

atrioventricular block III (not related to the study drug) within 24 hours after the procedure. There were two major amputations and one minor amputation among three patients in the placebo group compared with one major amputation and two minor amputations among three patients in the abciximab group.

No major bleeding event occurred. Overall, 17 patients in the abciximab group and nine patients in the placebo group had minor hemorrhagic complications, with an odds ratio of 2.9 (95% confidence interval: 1.04, 8.2; $P = .04$) in disadvantage of abciximab. There was a nonsignificant trend for more local bleeding in patients who received additional heparin infusion after the procedure (odds ratio, 1.51; 95% confidence interval: 0.44, 5.24; $P = .44$). All bleeding complications were limited to the access site. None of the patients had to be treated by means of red blood cell substitution or surgery, and none of the patients needed intensive care. Blood loss with a decrease in hemoglobin of less than 5 g/dL occurred in two patients who received abciximab and four patients who received placebo. Age, sex, serum creatinine level, and the size of the sheath did not have a significant influence on access site bleeding (Table 5). A false aneurysm occurred in six patients in each group; all were successfully treated by means of sonographically-guided compression. No case of thrombocytopenia owing to administration of abciximab was observed.

## DISCUSSION

The results of our trial demonstrate the safety and statistically significant effectiveness of abciximab for the improved primary patency and clinical outcome among patients with endovascular revascularization of long-segment femoropopliteal occlusions. Primary cumulative patency rates at 30 days and 6 months showed a comparable benefit, which underlines a durable treatment effect over 6 months of follow-up.

Endovascular treatment of femoropopliteal occlusions more than 5 cm long is associated with high early failure rates that range from 13% to 41% (23–25). Abciximab was hypothesized to be a promising adjunctive drug treatment to improve patency rates in this prothrombotic clinical situation. To our knowledge, Duda and colleagues (26) were the first to administer abciximab in a randomized trial in patients with acute femoropopliteal occlusions who were undergoing urokinase thrombolysis. Abciximab treatment resulted in faster thrombus dissolution and improved amputation-free survival compared with urokinase treatment alone. The effect of abciximab for both acute and chronic femoropopliteal occlusions was evaluated by Stavropoulos et al (27) in an uncontrolled series of 16 patients, 10 of whom were followed for 1 month, which suggested the feasibility and usefulness of abciximab in peripheral interventions and implicated the necessity of a prospective double-blind study to assess effectiveness and safety. The results of our randomized placebo-controlled trial demonstrate that abciximab is effective for both acute and chronic occlusions. The effect was seen in terms of patency and clinical outcome in the leg as expressed by the Rutherford score. The latter includes changes in the clinical stage that might be evoked by improvement of the macro- and microcirculation. In fact, a known advantage of the use of abciximab in patients with coronary heart disease is that the perfusion of small vessels is markedly improved by inhibition of microthrombosis (28–30).

In our study, postinterventional treatment with either ASA or VKA was allowed. Post hoc subgroup analysis cannot enable reliable conclusions in a relatively small number of included patients; however, an association between postprocedural VKA or ASA treatment in the abciximab and placebo groups, respectively, and patency rates was searched for by using a fixed effects model. The resulting odds ratios indicate that the favorable effect of abciximab on patency rates at the end of follow-up was enhanced by ASA treatment but not by VKA treatment. It seems that in this clinical situation platelet inhibition is the preferable treatment approach in comparison with anticoagulation, a finding that is consistent with those of previous studies on the investigation of the effect of antiplatelet versus anticoagulant therapy in patients undergoing femoropopliteal angioplasty (12,31).

Pooled data analysis from several trials—Evaluation of 7E3 (abciximab) in Preventing Ischemic Complications, or EPIC; Evaluation of Percutaneous Transluminal Coronary Angioplasty to Improve Long-term Outcome with Abciximab Platelet Glycoprotein IIb/IIIa Block-

ade, or EPILOG; and Evaluation of Platelet IIb/IIIa Inhibitor for Stenting—revealed the greatest beneficial effect of abciximab treatment in patients with diabetes (14,15,31,32). This observation could not be confirmed in our study, in which about one-fifth of the patients had diabetes. In contrast, fixed effects size model analysis suggests a possible stronger benefit for nondiabetic patients with peripheral arterial disease. However, cautious consideration of these results is required, because subgroups are small and the outcome of patients with diabetes was not a primary targeted goal.

In our study, patients had a high risk for reocclusion because of extended endothelial damage and localized prothrombotic states, which necessitated periinterventional treatment with standard doses of unfractionated heparin. Unfractionated heparin is the current antithrombotic agent of choice in peripheral vascular interventions, and it is generally associated with a local bleeding risk of approximately 5% (33). On the basis of earlier experience in patients with coronary disease as in the EPIC and EPILOG trials, it was expected that standard-dose heparin administration combined with adjunctive abciximab treatment would result in increased bleeding rates (14,15). This was not the case in our study population. The only risk factor for increased access site bleeding was treatment with abciximab. The lack of increased bleeding complications in patients who were administered standard-dose heparin in addition to abciximab might be explained by means of a number of precautionary measures that were undertaken, such as sheath removal immediately following intervention and manual puncture site compression for up to 30 minutes before applying compression bandage for 20 hours.

Factors limiting this trial were mainly the fact that it was a single-center trial and included both patients with acute-on-chronic and those with chronic occlusions, as well as the free choice in postprocedural secondary prevention with regard to ASA or VKA. A European multicenter trial that includes 420 patients with only chronic occlusions treated exclusively with platelet inhibitors is ongoing.

In conclusion, the results obtained in this randomized double-blind trial demonstrate the feasibility, effectiveness, and safety of adjunctive administration of abciximab in femoropopliteal long-segment occlusions. Until now it has been suggested that this type of lesion, defined as type D by the authors of the TransAtlantic Inter-Society Consensus guidelines (7), be treated either conservatively (ASA, risk factor management, daily walking) in patients with claudication or by means of peripheral bypass surgery in those with critical limb ischemia. The presented data of this study indicate that adjunctive treatment with abciximab might significantly contribute to the improvement of early- and midterm patency rates. Further evidence may be expected from an ongoing European multicenter, randomized, placebo-controlled trial on the evaluation of abciximab in the described therapeutic setting in a considerably larger number of patients.

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