A Double-Blinded Randomized Controlled Trial Comparing Eptifibatide Bolus Only Versus Bolus Plus Infusion In Patients Undergoing Primary Percutaneous Coronary Intervention For ST-Elevation Myocardial Infarction☆

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Highlights

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  Eptifibatide is commonly used in conjunction with heparin during high risk PCI with a recommended dose of initial weight based Bolus and at least 24 hours infusion

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  The goal of this study was to evaluate Bolus only arm in a double-blinded randomized control trial.

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  The primary PCI patients who received bolus eptifibatide were randomized to 75mg IV eptifibatide infusion (short-term protocol = group A) or placebo (group B) blindly.

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  There was no differences in the risk of access site ecchymosis, hematoma or major bleeding. Ischemic events and stent thrombosis rates were also similar.

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Our study suggests that using eptifibatide bolus only during PCI of patients with STEMI is safe and can be cost saving.

Abstract

Backgrounds

The use of eptifibatide combined with heparin during percutaneous coronary intervention (PCI) in patients presenting with ST-elevation myocardial infarction (STEMI) is recommended to be followed by continuous infusion. Recently, there are some suggestions that using bolus only may be sufficient and cost-effective but randomized trials are lacking.

Aims

The goal of this study was to evaluate these two approaches in a double-blinded randomized control trial.

Methods

The primary PCI patients who received bolus eptifibatide were randomized to 75 mg IV eptifibatide infusion or placebo blindly. The patients were followed up for the primary outcome of vascular or bleeding complications and secondary outcome of ischemic complications.

Results

330 patients (165 from each group) completed the study. The mean age was 57.67 ± 11.53 years and 77.3 % were male. Major bleeding was seen in 1 patient in each group. Hematoma occurred in 8.5 %. The relative risk of hematoma and ecchymosis in bolus plus infusion group to bolus only group were 0.988 (95 % CI: 0.486–2.006) and 1.032 (95 % CI: 0.729–1.459). Multivariate analysis confirmed no significant differences in the bleeding event. Furthermore, there was no significant difference in in-hospital death or any ischemic events. (Cath lab death: 1.4 % in bolus only vs zero % in the control group, $p = 0.217$, stent thrombosis was seen in one patient in each group).

Conclusion

There were no differences in the risk of access site ecchymosis, hematoma or major bleeding. Ischemic events and stent thrombosis rates were also similar. Our study suggests that using eptifibatide bolus only during PCI of patients with STEMI is safe and can be cost-saving.

Section snippets

Background

Primary percutaneous coronary intervention (PCI) has revolutionized the management of patients with ST-elevation myocardial infarction (STEMI) and is the routine practice in many centers if it is possible to be performed within 90 min of first patient contact [1]. Currently, antiplatelet therapy, including aspirin and a P2Y12 adenosine diphosphate (ADP) receptor antagonist is part of the standard PCI. Clopidogrel is among the first ADP antagonists introduced for platelet inhibition in PCI and

Materials and methods

The study was conducted between 2018 and 2020 in Shahid Rajaei Hospital, Alborz University, Karaj, Iran. Patients with chest pain within <12 h with 1 mm ST elevation in at least two leads were assessed to enter the study. The included patients were treated with primary PCI from the femoral artery access site. Our exclusion criteria were: a rejection of informed consent; history of sensitivity to eptifibatide, heparin, or aspirin; recent treatment with warfarin (INR > 2) or other anticoagulants;

Sample size calculation and data analysis

The sample size was calculated based on a pilot result assuming the incidence of ecchymosis or hematoma would be about 18 % in group A (bolus only) in comparison to 28.5 % in group B (bolus + infusion). With an alfa error of 0.05 and a beta error of 0.2, we needed approximately 163 patients in each group, which was expanded to 165 for our block randomization.

Analysis was done by SPSS software version 16.0 (SPSS Inc., Chicago, IL). One-sample Kolmogorov-Smirnov test and histograms were used to

Results

A total of 330 patients, including 165 patients from each group, were included in the study. Fig. 1 shows the flow chart of the participants. The mean age of the patients was 57.67 ± 11.53, and 255 (77.3 %) of them were male. Patients received a mean of 8.17 ± 1.32 h of eptifibatide infusion or normal saline as a placebo.

Table 1 shows the baseline characteristics of the two studied groups. Table 2 describes a comparison of procedures done on the two groups. The mean hospitalization time of our

Discussion

We compared a bolus prescription of eptifibatide with bolus plus short-term infusion in STEMI patients undergoing PCI in the presence of dual antiplatelet inhibition with oral aspirin and clopidogrel and anticoagulation with heparin. We found that major bleeding, the incidence of hematoma at the access site, and the incident of ecchymosis were not significantly different in the two studied groups (Table 3). Although ecchymosis surface area seemed more expansive in patients who received the

Study limitations

We conducted a single-center randomized clinical trial. Considering very low in-hospital mortality and major bleeding complications in our patients, we needed to enroll many more patients to show the Non-inferiority of one method to the other in terms of mortality or ischemic events. Enrolment of these patients was not possible in our area as a single-center considering the number of eligible patients and the costs of the study. Therefore, we may not conclude about the ischemic and bleeding

Conclusions

We randomly evaluated in a double-blinded fashion bolus eptifibatide vs bolus plus continuous infusion of eptifibatide in patients with STEMI undergoing primary PCI. The risk of access site ecchymosis and hematoma, death, and major bleeding was not significantly different between the two groups. Furthermore, ischemic events and stent thrombosis rates were similar. Our study suggests that using eptifibatide bolus only during PCI of patients with STEMI is safe and can lead to cost-saving without

CRediT authorship contribution statement

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Mohammad Reza Movahed M.D, Conceptualization, Data analysis, Writing, Reviewing, Editing.

Declaration of competing interest

None. We have no conflict of interests to disclose.

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