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Abciximab in elderly with Acute Coronary Syndrome invasively treated: Effect on outcome

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Abstract

Older age is an independent predictor of mortality after percutaneous coronary intervention (PCI) in patients with Non-ST elevation Acute Coronary Syndrome (ACS). GPIIb/IIIa inhibitors are proved to improve outcome in high risk patients, but conflicting data are available about the effects of these inhibitors in elderly. Accordingly, we studied a consecutive population of elderly patients undergoing PCI for Non-ST elevation ACS. A total of 500 patients were divided in: GPI group (247 pts; mean age 77±1.9 years) treated by stenting plus abciximab and, no GPI group (253 pts; mean age 77±2.4 years) treated by stenting alone. Propensity analysis was used to account for the nonrandomized use of GPIIb/IIIa inhibitors. During hospitalization, incidence of death was similar among groups (3.2% vs 4.6%) without difference regarding incidence of major (1.6% vs 1.1%) and minor bleedings (4% vs 3%). At long-term follow-up the rate of death was significantly lower in GPI group (4.5% vs 12.3%; $p=0.002$) as well as the rate of acute myocardial infarction (2.8% vs 11.1%; $p=0.0001$), and pre-PCI (5.7% vs 13.4%; $p=0.003$). Cox regression analysis identified abciximab use as an independent predictor of lower long-term major adverse cardiac event (MACE) after adjustment for propensity score (Exp (B) 0.620, 95%CI 0.394–0.976, $p=0.039$). Our results suggest that addition of abciximab to stenting improves outcome in elderly patients with Non-ST elevation ACS, leading to an absolute benefit for reduction of death and MACE, with an acceptable rate of major and minor bleedings.

Keywords: Elderly; Acute Coronary Syndrome; Coronary angioplasty; GPIIb/IIIa inhibitors

1. Introduction

Elderly are increasingly represented among patients with Acute Coronary Syndromes (ACS), and advanced age has been identified as an important risk factor for death and adverse outcome in patients with ACS invasively treated [1]. Although several data have demonstrated the prognostic benefit of early revascularization in ACS particularly in high risk patients, [2–4] elderly with ACS are less treated with invasive procedures than younger patients [5,6]. Besides, tough intravenous administration of platelet glycoprotein (GP) IIb/IIIa receptor antagonists has been showed effective in reducing ischemic complications in patients presenting with ACS and also during percutaneous coronary intervention (PCI) [2,6], elderly patients are less often treated with these agents [7–9]. Moreover administrations of GPIIb/IIIa inhibitors (GPI) in these patients are still controversial since elderly have traditionally been underrepresented in clinical

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trial of ACS [10]. Consistently with lack of available study and current uncertainties regarding use of GPIIb/IIIa inhibitors in elderly, we analyzed clinical outcome in a consecutive series of elderly patients with Non-ST-elevation ACS who underwent coronary stenting with or without use of the GPIIb/IIIa receptor antagonists abciximab.

2. Methods

2.1. Study population

All patients aged ≥75 years with Non-ST-ACS [11] undergoing PCI at Federico II University of Naples from January 2001 to December 2003 were included in the study and stratified according to the use of abciximab, a potent GPIIb/IIIa inhibitor [12–15].

2.2. PCI procedure, clinical and angiographic data analysis

PCI was performed according to the AHA/ACC guidelines, [16] through femoral approach using small size arterial sheaths (6F). Informed consent was obtained from each patient (or from their relatives in case of patient's inability) before coronary angiography. All patients received aspirin (500 mg intravenously) and heparin (50 IU/kg intravenously) before the procedure. Clinical risk profile and bleeding complications were evaluated according to the TIMI criteria [17,18] After baseline coronary angiography, abciximab was administered as a 0.25 mg/kg bolus intravenous, followed by 12 h of 0.125 μg/kg/min intravenous infusion. Therefore, all patients received abciximab at time of PCI and no patient was treated with an upstream strategy. Angiographic lesion morphology was classified according to AHA/ACC classification [19]. Antegrade perfusion of the treated vessel was graded by Thrombolysis in Myocardial Infarction (TIMI) criteria [20] and corrected TIMI frame count (cTFC) methods [21] The activated clotting time was maintained at ≥250 to 300 s during the procedure. Hemostasis of femoral artery access was obtained by Angioseal 6F, a mechanical closure device, [22] employed as a first choice in all suitable procedures, on the contrary, early sheath removal was strongly encouraged. All patients were on aspirin (325 mg daily) and ticlopidine (250 mg daily for 3 months) after stenting; adjunctive medications were given according to the individual patient's clinical status.

2.3. Clinical follow-up

Follow-up data were obtained by direct interview at our outpatient clinic or by telephone contact with the patients, their relatives or their referring physicians when necessary. Major adverse cardiac events (MACE) defined as cardiac death, acute myocardial infarction, and need for revascularization procedures (new PCI or coronary by-pass graft surgery) were recorded during hospital stay and at follow-up of 24±4 months after PCI. Follow-up was completed in all patients included in the study.

2.4. Statistical analysis

Continuous variables are presented as mean±standard deviation and categorical variables as absolute number and percent value. Differences between groups were assessed with ANOVA univariate for continuous variables and with a chi-square test with the Fisher exact test and odds ratio with 95% confidence intervals for categorical variables; p value <0.05 was considered significant. Propensity score analysis was performed using a stratified Cox regression with treatment strategy (i.e., PCI plus abciximab vs PCI alone) as a fixed dummy covariate and propensity score quartiles (propensity to treat with abciximab estimated by multivariable logistic regression) as a stratification variable. Results are reported as adjusted hazard ratio with associated 95% confidence interval (CI) and p values. Differences in event-free survival between the groups were evaluated by the Kaplan–Meier method, comparison was made using log-rank test. Cox regression analysis was performed in order to identify the independent predictor long-term survival. The computer program used was SPSS 12.0 (SPSS Inc., Chicago).

Table 1
Baseline clinical and angiographic characteristics

Variables	GPI (n=247)	No GPI (n=253)	p
Age (mean±SD) year	77±1.9	77±2.4	NS
Female sex (%)	28.2	23.1	NS
Family history of CAD (%)	31.5	29.9	NS
Hyperdislipidemia (%)	50	35.3	0.001
Diabetes (%)	26.9	25.6	NS
Hypertension (%)	65	51.3	0.002
Smoking (%)	35.3	39.1	NS
COPD (%)	51	47	NS
Chronic renal failure (%)	7.1	3.2	0.05
Previous anterior MI (%)	51.6	32	0.001
Previous PCI (%)	6.3	13	NS
Previous CABG (%)	11.3	5.9	0.05
Ejection fraction (%)	46.45±14.4	45.5±16	NS
TIMI risk score	6.5±1	4.6±1	0.005
LAD	78.2	60	NS
CX	21.3	9.1	NS
RCA	36.2	31.8	NS
Direct stenting	23.4	37.5	0.006
Multivessel disease	74.7	63.2	0.024
B2/C lesion	80	76	NS
Procedural success	93.3	95.5	NS
Use of Angioseal	86	88	NS

CAD: Coronary artery disease.
COPD: Chronic Obstructive Pulmonary Disease.
MI: Myocardial infarction.
PCI: Percutaneous coronary intervention.
CABG: Coronary artery by-pass graft.
TIMI: Thrombolysis in Myocardial Infarction.
LAD: Left anterior descending coronary artery.
CX: Left circumflex coronary artery.
RCA: Right coronary artery.

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3. Results

3.1. Baseline characteristics

Between January 2001 and December 2003, 540 patients aged ≥75 years underwent PCI at Federico II University for Non-ST-ACS. Of these 247 patients (46%) received abciximab at the operator's discretion. Thus, according with GPIIb/IIIa inhibitor administration, we divided the study population into: GPI group (247 pts; mean age 77±1.9 years; 71.8% male) treated by stenting plus abciximab and, no GPI (253 pts; mean age 77±2.4 years; 76.9% male) treated by stenting alone. Baseline clinical characteristics are listed in Table 1. Patients treated with abciximab were more likely to present with hypertension, hyperdislipidemia, chronic renal failure and previous myocardial infarction. Of note, TIMI risk score was significantly higher in patients treated with abciximab, remarking the worse clinical risk profile for this group of patients (Table 1). Medical management with antiplatelets (90% vs 88%), β-blockers (45% vs 48%), angiotensin-converting enzyme inhibitors (23% vs 20%) or calcium channel blockers (38% vs 36%) was similar in both groups after hospital discharge.

3.2. Angiographic results

Catheterization time was similar between groups and PCI was performed in all pts within 48 h from diagnosis of Non-ST elevated ACS. Accordingly with the higher risk profile, multivessel coronary disease was significantly higher in GPI treated patients, indicating the greater extension of coronary disease in elderly treated by abciximab (Table 1). Moreover, patients treated with the GPIIb/IIIa inhibitor showed the worse pre-procedural flow as indicated by a significantly higher cTFC pre-PCI (57±4 vs 41±2, $p<0.001$). Procedural success was similar in both groups and despite the pre-procedural difference we observed a significant improved perfusion in both groups (18±3 vs 16±2, p=NS). Finally, the use of Angioseal was similar between groups (Table 1).

3.3. In-hospital outcome

Hospitalization time was significantly lower in GPI group (5.3±1 vs 6.9±2 days; $p=0.02$). During hospital stay, incidence of death was similar among groups (3.2% vs 4.6%). Patients treated with abciximab showed a slight increased rate of major bleedings (1.6% vs 1.1%) and minor hemorrhagic complications (4% vs 3%) represented largely by access site bleedings. In particular, there were no retroperitoneal, pulmonary or intracranial hemorrhage in both groups but gastrointestinal and genito-urinary bleedings not requiring transfusion were more frequent in GPIIb/IIIa treated group.

3.4. Long-term outcome

The 24±4 months follow-up is reported in Figs. 1 and 2. During the follow-up interval, as regards to overall population, the rate of death was significantly lower in GPI group (4.5% vs 12.3%; RR=0.334, 95%CI 0.164–0.680, $p=0.002$) as well as the rate of acute myocardial infarction (2.8% vs 11.1%; RR=0.234, 95%CI 0.100–0.547, $p=0.0001$), and pre-PCI (5.7% vs 13.4%; RR=0.387, 95% CI 0.202–0.741, $p=0.003$). No difference was found in the

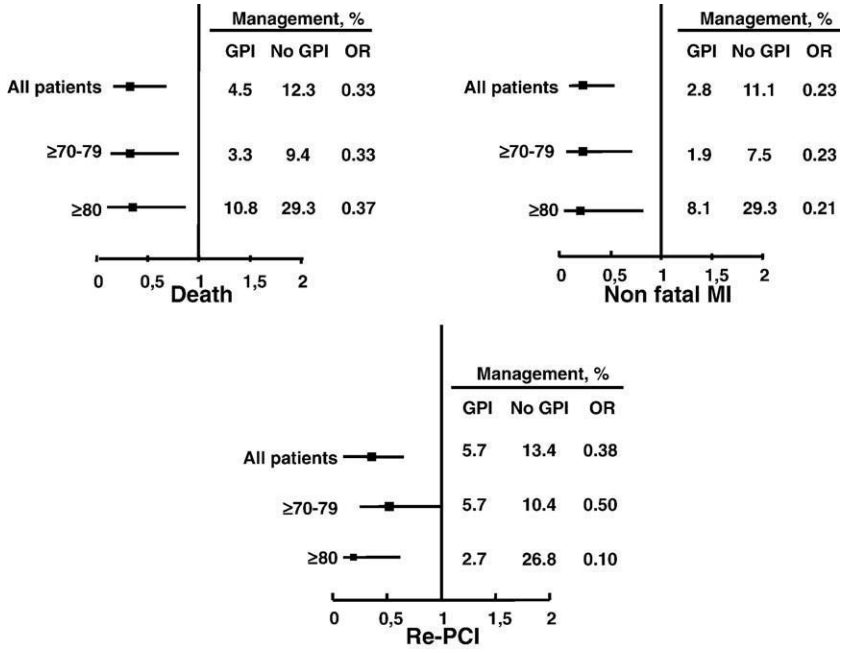

Fig. 1. Long-term follow-up. This figure reports the incidence of death, non-fatal MI and pre-PCI at long-term follow-up in the two groups. Patients treated with abciximab showed a significant reduction in any considered adverse events compared with patients treated with stenting alone. This difference was confirmed also in patients divided by age.

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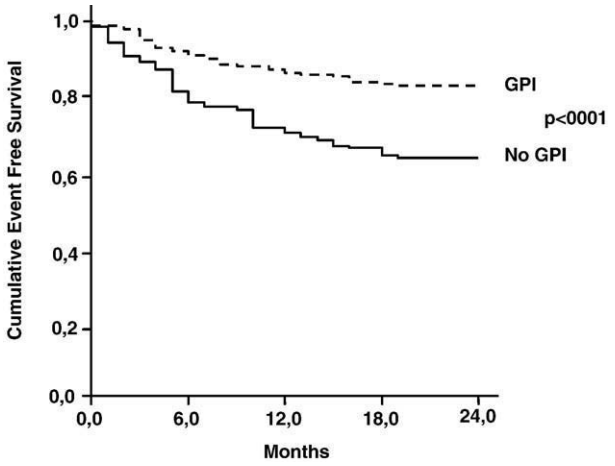

Fig. 2. Kaplan Kaplan–Meier analysis on event-free survival. Analysis of cumulative MACE in the two groups of patients. Elderly treated with PCI and abciximab showed a significant reduction in overall MACE.

rate of CABG at follow-up between groups (3.2% vs 5.2%, p=NS). To gain further inside insight into the effect of GPIIb/IIIa inhibitors on age, we analyzed the incidence of MACE according to the age. As reported in Fig. 1, the effect of abciximab on outcome was evident in all patients independently from their age. The Kaplan Kaplan–Meier analysis on cumulative MACE (Fig. 2) showed the significant improvement in event-free survival rate for this group of patients (p=0.0001), and by Cox regression analysis the only independent predictor of better prognosis was abciximab administration (Exp (B) 0.475, 95%CI 0.264–0.854, p=0.013). Furthermore, to account for the nonrandomized nature of abciximab use during PCI, propensity analysis was performed to model the GPIIb/IIIa inhibitor use. Abciximab use was an independent predictor of lower long-term MACE after adjustment for propensity score and the combination of propensity score and clinical and angiographic characteristics (Exp (B) 0.620, 95%CI 0.394–0.976, p=0.039).

4. Discussion

Our results suggest that association of abciximab to stenting in elderly patients with Non-ST elevation ACS improves outcome by reducing MACE with a slight increase of bleedings.

Advanced age has been associated with an adverse outcome after an episode of Non-ST-elevation Acute Coronary Syndrome [1,23,24] and elderly patients represent a high risk population for coronary revascularization, being advanced age an independent predictor of overall mortality often associated with more diffuse and severe coronary artery disease [25]. Although older patients could benefit more by a safe and effective revascularization, [26] in current clinical practice, older patients with ACS are less likely to undergo invasive procedures and to receive GPIIb/IIIa inhibitors than younger patients [1,5,6,23,24,27]. Clinicians' reluctance to use an invasive strategy for elderly patients with ACS may be related to higher risk for complications and by the underrepresentation of such patients in randomized trials [8–11]. Sadeghi et al. [28] evaluated the safety profile of GPIIb/IIIa inhibitors (73% eptifibatide) in a consecutive series of octogenarians undergoing PCI for ACS or MI. Octogenarians treated with GPIIb/IIIa inhibitors had a higher incidence of access and non-access site bleedings and longer hospital stay, probably due to the higher risk of patients as suggested by the authors, although GPIIb/IIIa treatment does not portend any additional and independent risk of transfusion or intracranial hemorrhage. In our study we found an acceptable rate of major bleedings in both groups of patients after PCI and compared it to the study of Sadeghi et al., we found a lower rate of access site bleedings despite the high risk profile of GPIIb/IIIa treated patients. The lower rate of bleedings is responsible of the reduction of hospitalization time. It is conceivable that a synergistic strategy of weight-adjusted dose of heparin, small size arterial sheaths, continuous monitoring of ACT and mechanical hemostatic device reduces vascular access bleedings and in-hospital complications.

Recently, De Servi et al. [25] compared outcome of invasive vs conservative strategy in a prospective registry of patients with Non-ST elevation ACS. GPIIb/IIIa inhibitors (predominantly tirofiban and eptifibatide) were used less frequently in elderly patients and these patients had a more unfavorable 30 30-day-outcome compared with younger patients with the higher rates of death (6.4% vs 1.7%) and acute myocardial infarction (7.1% vs 5%), confirming elderly as a very high risk population among patients with ACS. We performed our study in a consecutive group of elderly (>75 years) with Non-ST elevation ACS undergoing stenting with and without administration of GPIIb/IIIa receptor inhibitors. Elderly patients receiving abciximab showed a higher risk clinical profile as indicated by higher TIMI risk score and more severe flow impairment as indicated by the worse pre-procedural cTFC. Furthermore these patients were more likely to have multivessel disease thus suggesting that operators selected "higher risk" patients for adjunctive GPI therapy. Despite the higher risk profile and the most severe flow impairment, addition of abciximab to stenting results in similar post-procedural cTFC between the two groups. A possible beneficial effect on outcome in subjects treated with abciximab could be the prevention of microembolization during stenting deployment or other effects of this agent that can interfere with microcirculation [29]. Accordingly, in our study after stenting and abciximab administration, the cTFC was significantly improved and thus such preservation of microcirculation could contribute to explain the improved outcome. Similar data have been reported by Antoniucci et al. [30] in the setting of acute MI.

This is a retrospective, nonrandomized study and selection bias or the possibility that the success of the procedure was a "marker" of some physiologic or anatomic variable, that made the individual less likely to have a recurrent ischemic event or to

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die from it, must be considered. Finally this study deals with patients enrolled in a time window in which only ticlopidine was available in our country and no clear cut data confirming the superiority of an upstream use of GPIIb/IIIa inhibitors were available, therefore potential beneficial effects of a strategy combining clopidogrel and upstream glycoprotein IIb/IIIa antagonists should be considered.

In conclusion, the result of this study suggests that addition of abciximab to stenting improves outcome in elderly patients with Non-ST elevation Acute Coronary Syndrome, leading to an absolute benefit for reduction of death, non-fatal myocardial infarction and needs of new revascularization, with a low rate of major and minor bleedings.

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