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ProAcor®: Registry to Evaluate Prospective Ambulatory Cardiological Structured Care in Acute Coronary Syndromes

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SYNOPSIS

ProAcor®: Registry to Evaluate Prospective Ambulatory Cardiological Structured Care in Acute Coronary Syndromes

The ProAcor Study (NCT01490645) assessed the acceptance and effectiveness of a structured patient management program over 12 months in patients who were discharged from hospital after an acute coronary syndrome (ACS) event into ambulatory cardiologal care.

The program comprised patient documentation with a specific instrument (BNK cardiac pass with visit scheduling) done jointly by the hospital physician and the office-based cardiologists, the definition of treatment targets and the structured information of patients in order to optimise adherence to therapy.

Thirty-six hospitals and 60 office-based cardiologists participated in ProAcor. Adult patients were eligible for participation, if they provided their written informed consent, and were hospitalized due to STEMI, NSTEMI or, UA.

The full analysis set of the study comprised all patients with written informed consent for whom at least 1 visit was documented (n= 1003). Among them, 444 had STEMI, 396 NSTEMI, 152 UA, and 11 were unclassified (evaluable data set n= 992 patients). Of the 1003 patients, 887 (88.4%) had at least one follow-up visit, while 116 (11.6%) had none. A total of 798 patients (79.6%) were completed as per protocol.

653 patients (73.6%) were males and 234 (26.4%) were females. Mean age of patients was 61.7 ± 11.6 years overall; it was somewhat lower in the STEMI group (58.9 ± 11.2 years) compared to the NSTEMI group (64.0 ± 11.6 years) and the UA group (64.3 ± 10.9 years), respectively. The most frequently noted concomitant diseases were arterial hypertension (72.6%), hyperlipoproteinaemia (59.2%), diabetes mellitus (22.2%) and renal insufficiency (7.2%). Current smoking was noted in 29.1% of patients, previous smoking in 27.6%. Valve disorders were reported in 6.8%, and heart rhythm disorders (most frequently atrial fibrillation) in 7.4%. Overall, 136 patients (15.3%) reported previous cardiac events, which were classified in 23 patients as STEMI, in 45 patients as NSTEMI, and in 64 patients as angina pectoris, respectively. Patients in the NSTEMI group tended to have a higher prevalence of concomitant diseases and cardiovascular risk factors compared to patients in the STEMI and UA groups, respectively.

After the ACS index event, patients were discharged from the acute hospital after 6.8 ± 8.4 days (median 6.0). Almost all patients (n= 859; 96.8%) received any cardiac medication after the index event. Drug classes most frequently prescribed were beta blockers in 809 patients

(91.2%), CSE inhibitors (statins) in 774 patients (87.3%), and ACE inhibitors in 611 patients (68.9%). Overall, prescribing rates of cardiac medication was higher in STEMI and NSTEMI patients, respectively, compared to UA patients.

During follow-up treatment rates with cardiac medication remained high in all groups (at least one drug in 857 patients (99.0%) at three months, in 829 patients (99.5%) at six months, and in 795 patients (99.6%) at 12 months.

As during the acute hospital stay, beta blockers were the leading drugs followed by CSE inhibitors (statins), and inhibitors of the RAS (aldosterone antagonists, ACE inhibitors, AT_1 blockers). There were no major changes in prescription rates of the individual drug classes during follow-up.

Treatment rates with antiplatelet drugs remained high during the study follow-up. Of the evaluable patients at each visit, 812 patients (93.8%) after three months, 772 (92.7%) after six months, and 682 patients (85.5%) after 12 months received ASA or any of the P2Y12 inhibitors. Dual antiplatelet therapy (DAPT) was reported in 788 patients (91.0%) at three months, 750 patients (90.0%) at six months, and 661patients (82.8%) at 12 months, respectively. For all time points, rates of antiplatelet drugs (any or DAPT) were higher in the STEMI group compared to the NSTEMI and UA groups.

Mean participation time in the management program was 11.4 ± 2.4 months overall. One year after the inclusion, a total of 798 patients (90.0%) still participated in the patient management program, while 89 patients (10.0%) did not. Dropout rates were higher in the STEMI group (11.1%) and the UA group (12.0%), respectively, compared to the NSTEMI group (8.1%).

Reasons for premature withdrawal from the program in the 89 patients were change of their medical doctor in 10 cases, withdrawal of informed consent in 14 cases, patient lost to follow-up in 57 cases, death of the patient in three cases, and patient move to another location in five cases.

On the EQ-5D visual analogue scale, patients rated their best possible state of health at 76.5±17.5 at the 3-month follow-up visit, at 77.3±17.2 at the 6-month follow-up visit and at 77.3±16.0 at the 12 month follow-up visit. The calculated quality of life index of the EQ-5D was 0.9±0.2 at the 3-month follow-up visit, 0.9±0.2 at the 6-month follow-up visit and 0.9±0.2 at the 12 month follow-up visit. Thus, QoL remained unchanged during the study.

Physicians rated the compliance of their patients after 12 months in 793 patients (100%). According to their assessment, 698 patients (88.0%) were *always* compliant (i.e. seven days a week), 90 (11.3%) *mostly* compliant (4 to 6 days a week), 4 patients (0.5%) rarely compliant (1-3 days a week), and one patient *never* compliant (0.1%). There were no relevant differences in patient compliance in the STEMI, NSTEMI or UA groups, respectively.

During follow-up, among the evaluable patients 3 died (0.3%). All deaths occurred in the NSTEMI group. The vital status (dead or alive) could not be assessed in 15 patients (1.7%). Thus, the total mortality including the unclear cases was 2.0% during follow-up.

New cardiac events occurred in 128 patients (14.4%) during the full observational period. 78 patients (9.0%) had the new event within the first 3 months, 30 patients (3.6%) between 3 and 6 months, and 35 patients (4 .4%) between 6 and 12 months. The rates of new cardiac events was higher in the STEMI group (62 patients, 15.2%) compared to the NSTEMI group (51 patients, 14.7%) and the UA group (15 patients, 11.3%), respectively. The majority of reported events were angina pectoris (86 patients, 67.2%), STEMI (20 patients, 15.6%), NSTEMI (17 patients, 13.3%), or a combination of these events (5 patients, 3.9%). 18 of the 20 STEMI events occurred in patients in the STEMI group.

Overall, considering the full follow-up period after 12 months, 600 patients (67.6%) were able to work, while 285 (32.1%) were not (2 patients not specified). A total of 338 patients (38.1%) were hospitalised within 12 months. The hospitalisation rates were higher in the STEMI group (159 patients, 39.1%) and NSTEMI group (136 patients, 39.2%) than in the UA group (43 patients, 32.3%). 541 patients (61.0 %) received rehabilitation measures within 12 months. The rates of patients receiving rehabilitation measures were much higher in the STEMI group (302 patients, 74.2%) compared to the NSTEMI group (201 patients, 57.9%) and the UA group (38 patients, 28.6%).

No specific safety assessments were made in the context of this observational study.

In conclusion, the adherence of patients to the structured patient management program was high. Further, the 1-year mortality of only 2.0% was remarkably low (for comparison in the MONICA study 13.3%). Quality of life in patients after an ACS syndrome in office-based cardiological care was high and the rate of reported problems in various domains comparatively low.