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REVIEW ARTICLE

Congress of American College of Cardiology (New Orleans, 2019): results of clinical trials

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The article contains a report on 18 most important clinical trials that represented during scientific sessions of the American College of Cardiology held in New Orleans, US, March 16–18, 2019.

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Last congress of American College of Cardiology was held in New Orlean, Louisiana March 16–18 2019.

New guidelines of American College of Cardiology/ American Heart Association on primary prevention of cardiovascular diseases were discussed [1]. This document summarized the most important studies on the atherosclerosis-related health problems (acute coronary syndromes, myocardial infarction (MI), stable and unstable angina, arterial revascularization, stroke/transient ischemic attack, peripheral arterial disease) and also heart failure and atrial fibrillation (AF). The guideline emphasizes coordination of patient and physician with interdisciplinary approach to the implementation of recommended preventive strategies based on social health determinants, barriers of medical care, limited medical knowledge, financial difficulties, cultural influences, the level of education and other social and economic risk factors, related to short- and long-term targets in healthcare.

Traditionally, congress participants were most interested in the results of new randomized clinical trials, which were presented during the scientific

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sessions of the Late-Breaking Clinical Trials and Featured Clinical Research. This article summarizes the results of most important clinical trials.

Myocardial Infarction

The **SAFARI-STEMI** [2] study included patients with ST-segment evaluation myocardial infarction during the first 12 hours after the first symptoms who underwent primary percutaneous coronary intervention (PCI) and were randomized to radial access (n = 1,136) versus femoral access (n = 1,156). The trial was terminated early due to futility in detecting a difference in the primary outcome (all-cause mortality at 30 days) according to treatment strategy — it was 1,5 % in radial assess group and 1,3 % in femoral assess group (p=0,69). Secondary outcomes were also detected with comparable frequency in radial and femoral assess group — reinfarction: 1.8 % for radial vs. 1.6 % for femoral (p = 0.83), stroke: 1.0 % for radial vs. 0.4 % for femoral (p = 0.12), death, reinfarction, or stroke: 4.0 % for radial vs. 3.4 % for femoral (p = 0.45), definite/probable stent thrombosis: 1.5 % for radial vs. 1.1 % for femoral (p = 0.83), non-coronary artery bypass grafting TIMI major bleeding: 1.1 % for radial vs. 1.3 % for femoral (p = 0.74).

The authors could not show the advantages of radial assess compared with femoral assess in patients with ST-segment elevation MI after PCI. Operators and catheterization laboratories can choose any assess depending on clinical situation and priorities.

The **TREAT** randomized study included patients who received fibrinolytic therapy for ST-segment elevated MI and were randomized to delayed ticagrelor (n = 1,913) versus clopidogrel (n = 1,886) therapy.

Combined primary outcome (cardiovascular mortality, MI, stroke/transient ischemic attack, recurrent ischemia, or other arterial thrombotic events) at 12 months occurred in 8.0 % with ticagrelor vs. 9.1 % with clopidogrel (p = 0.25). The Authors concluded the same effectiveness and safety of ticagrelor and clopidogrel in patients under 75 years with ST-segment elevated MI who underwent fibrinolytic therapy.

During the **CODIACS-QOL** study patients with acute coronary syndrome 2–12 months ago were randomized to depression screening/notification of results/treatment (n = 499) versus depression screening/notification of results (n = 501) versus no screening (n = 500). The depression was detected in 7,6 % and 6,6 % of patients from first and second group, respectively. There was no difference in the change in quality-adjusted life-years from baseline to 18 months between the three groups (p = 0.91), in depression-free days (p = 0.63) and mortality. Thus, depression screening in patients with recent acute coronary syndrome was ineffective and depression screening guidelines may need to be reconsidered.

Heart rhythm disturbances

Catheter ablation is being used to maintain sinus rhythm in patients with AF because it is thought to be more effective than drug antiarrhythmic therapy. At the same time, there are no data of large randomized clinical trials confirming the hypothesis of long-term outcomes improvement (mortality and stroke risk reduction) using AF ablation compared with drug antiarrhythmic therapy.

The **CABANA** trial included 2204 patients with paroxysmal (42,9 % of cases) and persistent (57,1 %) AF aged 65 years and over or under 65 years with over 1 stroke risk factor and were randomized to either catheter ablation (n = 1,108) or drug therapy (n = 1,096) according to valid recommendations. 90,8 % of patients from catheter ablation group underwent this procedure and 19,4 % two times due to its ineffectiveness. 301 patients (27,5 %) from drug therapy group also underwent catheter ablation during treatment. During 48,5 month median follow-up the primary outcome (death, disabling stroke, serious bleeding, or cardiac arrest) based on treatment received appeared in ablation vs. drug therapy groups, 8 % vs. 9.2 % (hazard ratio (HR) 0.86, with 95 % confidence interval (CI) 0.65–1.15, p = 0.303), death — 5.2 % vs. 6.1 % (HR 0,05 with 95 % CI from 0,60 to 1,21; p=0,377) death or cardiovascular hospitalization — 51.7 % vs. 58.1 % (HR 0.83 with 95 % CI from 0.74 to 0.93; p=0.001). Among serious adverse effects in catheter ablation group cardiac tamponade (0.8 %), hematomas (2.3 %) and pseudoaneurysms (1.1 %) appeared and thyroid dysfunction (1.6 %) and proarrhythmia (0.8 %) — in drug therapy group. The assessment of life quality according to AFEQT and MAFSI questionnaires 12 months after randomization showed better results in catheter ablation group (p < 0,001) [6].

Thus, the results of this important trial indicate that ablation is not superior to drug therapy. On the other hand, patients with AF randomized for catheter ablation had lower frequency of adverse effects and the migration of patients from one group to another should also be taken into account when interpreting the results of the trial.

It is widely known that alcohol consumption can cause AF. **Alcohol-AF** is first randomized controlled

study that included patients with paroxysmal and persistent AF and regular moderate alcohol consumption (16 drinks per week on average) were randomized to abstinence (n = 70) versus usual consumption (n = 70). Patients received comprehensive rhythm monitoring via an implantable loop recorder or existing pacemaker and the AliveCor mobile phone app in conjunction with Holter monitoring. During 6-months follow-up atrial fibrillation recurrence occurred in 53% of the abstinence group compared with 73% of the usual consumption group (p = 0.004) and mean atrial fibrillation burden was 5.6% of the abstinence group compared with 8.2% of the usual consumption group (p = 0.016) and atrial fibrillation hospitalization — 9% of the abstinence group compared with 20% of the usual consumption group (p = 0.053). Abstinence group also had reduced clinical manifestation of AF (p<0.05), body mass index (p=0.03) and arterial pressure level (AP). Patients with recurrent AF are recommended to reduce or terminate alcohol consumption.

During the **COACT** study [8] patients with out-of-hospital cardiac arrest who did not have ST-segment elevation on electrocardiogram post–return of spontaneous circulation were randomized to either emergent angiography (n = 273) or delayed angiography after neurological recovery (119,9 hours on average, n = 265). PCI was performed if indicated. The primary outcome (survival to 90 days) for immediate vs. delayed angiography, was 64.5% vs. 67.2% (HR 0.89 with 95% CI from 0.62 to 1.27; p = 0.51). There were no significant differences during 90-days follow-up between normal survival parameters, including mild / moderate neurological disability, myocardial damage, duration of inotropic support, shock markers, recurrence of ventricular tachycardia, duration of mechanical ventilation, major bleeding, acute renal damage, need for renal replacement therapy, neurological status during discharge from the intensive care unit. The results of this trial indicate that 90-days survival rates of immediate angiography with an intent to revascularize are not superior to delayed angiography among patients with out-of-hospital cardiac arrest with no ECG evidence of ST-segment elevation.

The Apple Watch and corresponding Heart Study app uses photoplethysmography to intermittently measure blood flow activity and detect subtle changes that might indicate an irregular heartbeat. When it is detected they create tachogram that demonstrates irregular heart rhythm and initiates more frequent monitoring. If the next tachograms are normal, the initial measurement frequency is returned. In case if five of the six tachograms detected irregular heart rhythm during 48 hours, the patient is notified.

The aim of **Apple Heart** [9] study was to identify patients with irregular pulse watch notification who have AF on a subsequent electrocardiogram (ECG) patch. A total of 419,297 people without documented AF/ atrial flutter or be taking anticoagulants self-enrolled in the study. During the 8-year follow-up a pulse notification was received by 2,161 participants (0.52 percent). Notification rates were most frequent in participants over 65 years (3.14% percent) and lowest among those under 40 (0.16 percent). Patches were sent to 658 participants and 450 were returned and included in the analysis. Only 0.26% of senile patients and 0.004% of young patients were detected with AF longer than 30 seconds for the first time (primary endpoint).

The results of the study were criticized by experts, who noted an overload of information, and cardiac arrhythmias overdiagnosis that caused excessive anxiety and could initiate unnecessary treatment.

Antithrombotic therapy

In a 2×2 factorial design **AUGUSTUS** [10] study, patients with atrial fibrillation undergoing coronary revascularization were randomized to either 6-months treatment of apixaban (n = 2,306) or vitamin K antagonist (n = 2,308), or aspirin in combination with P2Y12 inhibitor (n = 2,307) or matching placebo (n = 2,307).

During the 6-month follow-up the primary safety outcome (clinically relevant nonmajor bleeding) for apixaban vs. vitamin K antagonist, was 10.5% vs. 14.7%, (HR 1.89 with 95% CI from 1.59 to 2.24; p < 0.0001) and for aspirin vs. placebo, was 16.1% vs. 9.0% (HR 1.89 with 95% CI from 1.59 to 2.24; p < 0.0001). The frequency of death or hospitalization and ischemic events (stoke, MI, thrombosis, acute revascularization) were 23.5% lower in apixaban group compared with vitamin K antagonist (27.4%) (HR 0.83 with 95% CI from 0.74 to 0.93; p=0.002). The frequency of death, hospitalization and ischemic events was the same in aspirin and placebo groups. Among patients with AF with recent acute coronary syndrome or PCI, adding apixaban without aspirin to a P2Y12 inhibitor resulted in lower bleeding compared with vitamin K antagonist, aspirin or its combination.

The AUGUSTUS study proved that the combination of direct oral anticoagulant and P2Y12 receptor inhibitor, usually clopidogrel is safer than three-drug therapy (warfarin, clopidogrel and aspirin) for such patients.

During the **SYOPDAPT-2** study [11] patients undergoing PCI with Xience series cobalt-chromium everolimus-eluting stents were randomized to 1 month of dual antiplatelet therapy (DAPT) followed by clopidogrel monotherapy for 5 years (n = 1,523) versus 12 months of DAPT followed by aspirin monotherapy for 5 years (n = 1,522). During 1-year follow-up the primary outcome (death, myocardial infarction (MI), stent thrombosis, stroke, TIMI major/minor bleeding) occurred in 2.4% of the 1-month DAPT group compared with 3.7% of the 12-month DAPT group (p = 0.04). The frequency of ischemic complications (death, MI, stent thrombosis, or stroke) at 1 year: 2.0% of 1-month DAPT group compared with 2.5% of 12-month DAPT group (p for noninferiority = 0.005), and the frequency of hemorrhagic complications was significantly lower in 1-month group compared with 12-month group, respectively (TIMI major/minor bleeding at 1 year: 0.4% vs. 1.5%, p = 0.004; Bleeding Academic Research Consortium 3 or 5 bleeding at 1 year: 0.5% vs. 1.8%, p = 0.003).

The clinical benefit of a 1-month DAPT in patients after PCI was significantly higher compared with 12-month DAPT that is due to a reduced risk of hemorrhagic complications with similar frequency of ischemic complications.

During the **SMART-CHOICE** [12] study patients after PCI with everolimus-eluting stents were randomized to either short-duration DAPT (3 months, n=1495) or longer duration DAPT (12 months, n=1498). The primary outcome (all-cause death, MI, or stroke) at 12 months, for 3 months vs. 12 months of DAPT, was 2.9% vs. 2.5%, (p=0.46), all-cause death: 1.4% vs. 1.2%, (p = 0.61), MI: 0.8% vs. 1.2%, (p = 0.28), stent thrombosis: 0.2% vs. 0.1%, (p = 0.65), bleeding Academic Research Consortium (BARC) 2–5: 2.0% vs. 3.4% (p = 0.02) for 3 months and 12 months of DAPT, respectively.

The results of this trial indicate that short-duration DAPT (3 months) is noninferior to longer-duration DAPT (12 months) among unselected patients undergoing PCI with everolimus-eluting stents. However, it is important that with acute coronary syndrome need longer duration of DAPT versus patients with stable ischemic heart disease.

Major bleeding that occurs spontaneously or is associated with emergency invasive procedures is an issue during ticagrelor and another antiplatelet drugs treatment. Platelet transfusion cannot eliminate antiplatelet effects of ticagrelor. That is why an invention and first trials of quick-acting antidote to ticagrelor are very important.

In phase 1 of randomized, double-blind, placebo-controlled study, the efficacy of intravenous infusion of **PB2452**, monoclonal antibody fragment that binds to ticagrelor and reverse its antiplatelet effect, was estimated [13]. The function of platelets was determined in 64 healthy volunteers before, 48 hours after ticagrelor consumption, and after PB2452 or placebo infusion using optical aggregometry, a platelet reactivity test, and analysis of vasodilator-stimulated phosphoproteins. intravenous infusion of PB2452 (8, 12, 16 hours) was accompanied by increased platelet function compared with placebo. Reversal of ticagrelor was noted within 5 minutes and was sustained for 20 hours ($p < 0.001$ after Bonferroni correction). Adverse effects of PB2452 included only bruising of infusion site.

Valvular heart disease

The risks of transcatheter aortic valve replacement compared with surgical aortic valve replacement are similar among high- or mid-risk patients with aortic stenosis. During **PARTNER 3** trial 1000 low-risk patients with severe aortic stenosis (average age 73 years) were randomized to transcatheter aortic valve replacement or surgical aortic valve replacement. The primary outcome (all-cause mortality, stroke, or rehospitalization) at 1 year, occurred in 8.5% versus 15.1% (HR 0.54 with 95% CI from 0.37 to 0.79; p = 0.001), all-cause mortality — 1.0% versus 2.5% (HR 0.41 with 95% CI from 0.14 to 1.17), stroke — 1.2% versus 3.1% (HR 0.38 with 95% CI from 0.15 to 1.00), rehospitalization — 7.3% versus 11.0% (HR 0.65 with 95% CI from 0.42 to 1.00) in transcatheter aortic valve replacement or surgical aortic valve replacement groups, respectively. During the first 30 days patients from transcatheter aortic valve replacement group had lower rate of stroke (p = 0.02), death from stroke (p=0.01), new-onset AF at 30 days: (p < 0.001), death or low Kansas City Cardiomyopathy Questionnaire score at 30 days SAVR (p < 0.001), reduced admission period (p < 0.001) compared with surgical aortic valve replacement group. The groups did not duffer by vascular complications (2.2% vs. 1.5%), permanent pacemaker (6.6% vs. 4.1%), moderate to severe paravalvular aortic regurgitation (0.8% vs. 0%). It is also remarkable that patients from surgical aortic valve replacement group had lover aortic valve pressure gradient at 30 days (11.2 versus 12.8 mm Hg), lower rate of left bundle brunch block at 1 year (8.0% vs. 23.7% HR 3.43 with 95% CI from 2.32 to 5.08) compared with transcatheter aortic valve replacement group.

The main study limitation was the duration of follow-up (1 year), that complicates assessment of delayed valve destruction. The control of younger patient's condition and echocardiography parameters should last for at least 10 years.

The **Evolut** study [15] included 1403 low-risk patients with severe aortic stenosis who underwent transcatheter aortic valve replacement with self-expanding CoreValve compared with surgical aortic valve replacement. After 12-months follow-up of 850 patients the primary endpoint (all-cause mortality or disabling stroke) for transcatheter aortic valve replacement vs. surgical aortic valve replacement at 24 months, was 5.3% vs. 6.7%, respectively. During the first 30 days lower rates of disabling stroke (0.8% vs. 2.6%), bleeding (2.4% vs. 7.5%), acute kidney injury (0.9% vs. 2.8%), AF (7.7% vs. 35.4%), higher rate of moderate to severe aortic regurgitation (3.5% vs. 0.5%), pacemaker implantation (17.4% vs. 6.1%) were detected in transcatheter or surgical aortic valve replacement groups, respectively. 12 months after transcatheter aortic valve replacement group had lower aortic valve pressure gradient (8.6 vs. 11.2 mm Hg) and mean effective orifice area (2.3 cm 2 vs. 2.0 cm^2).

Authors of Evolut and PARTNER 3 study suggest to use transcatheter aortic valve replacement system not as the alternative for surgical aortic valve replacement, but as fist-line treatment in patients with severe aortic stenosis.

Heart failure

The open-label **COAPT** [16] study included patients with II–IV class of HF according to NYHA classification and grade 3–4+ MR who remained symptomatic despite maximally tolerated guideline-directed medical therapy. Patients were randomized to either MitraClip plus guideline-directed medical therapy (n = 302) or therapy alone (n = 312). The primary effectiveness endpoint (HF hospitalization at 24 months) for MitraClip + guideline-directed medical therapy vs. guideline-directed medical therapy, was 35.8% vs. 67.9% (HR 0.53, with 95% CI from 0.40 to 0.70, p < 0.001), the primary safety endpoint (freedom from device-related complications at 12 months) was 96.6% for MitraClip (p < 0.001).

All-cause mortality was registered in 29.1% vs. 46.1% (HR 0.62 with 95% CI from 0.46 to 0.82, p < 0.001), death or HF hospitalization — in 45.7% vs. 67.9% (p < 0.001), cardiovascular death — 29.1% vs. 46.1% (p < 0.001), stroke — 4.4% vs. 5.1% (p = 0.93), left ventricular assist device or heart transplant — 4.4% vs. 9.5% (p = 0.01) in MitraClip + guideline-directed medical therapy vs. guideline-directed medical therapy groups, respectively. MR severity improved by ≥2 grades: 84.1% vs. 15.9%, p < 0.0001. Mean Kansas City Cardiomyopathy and SF-36 life quality questionnaires at 24 months showed the superiority of MitraClip + guideline-directed medical therapy group. Thus, survival moderately improved at 24 months registered in 36.4% vs. 16.6% (p < 0.001) and substantially improved in 29.1% vs. 11.7% (p < 0.001).

The aim of **Hopeful Heart** trial [17] was to evaluate collaborative care for co-morbid heart failure and depression compared with usual care among patients recently hospitalized for heart failure. Patients with recent hospitalization for heart failure who screened positive for depression were randomized to the 'blended' group (collaborative care for heart failure and depression that included physiatrist, cardiologist, internist and nurse; n = 250) versus 'enhanced usual care' group (collaborative care for heart failure alone that included cardiologist, internist and nurse; n = 250) versus 'usual care' group (usual care for heart failure and depression; n = 125). There was also a control group that screened negative for depression (n = 125). There was an improvement in health-related quality of life at 12 months for blended care versus usual care (p = 0.002), improvement in mood symptoms (OR 0.47, p < 0.0001), no difference in readmission (p = 0.49) and mortality (p = 0.79) between the groups.

The **MOMENTUM 3** Final Report trial [18] included 1028 patients with severe progressive heart failure who regardless of treatment target (heart transplantation or palliative surgery) were randomized to either left ventricular centrifugal-flow pump (HeartMate 3, n = 516) or axial-flow pump (Heartmate II, n = 512). 61% of patients were ineligible for transplantation and 86% were on intravenous inotropic therapy. Characteristics of the centrifugal-flow pump are wide blood passages to reduce shear stress, no mechanical bearings to reduce friction, and intrinsic pulse to prevent thrombosis. Patients in both groups received aspirin and warfarin (target international normalized ratio, 2.0–3.0). The primary outcome (survival free from disabling stroke or reoperation to replace/remove a malfunctioning device) at 24 months, occurred in 76.9% of the HeartMate 3 vs. Heartmate II 64.8% of the axial-flow pump group (HR 0.84 with 95% CI from 0.78 to 0.91; p < 0.001) and replace-

ment of malfunctioning device was needed in 2.3% vs. 11.3% of cases, respectively. Overall survival at 24 months was 79.0% in the centrifugal-flow pump group vs. 76.7% in the axial-flow pump group (p = 0.37), any stroke at 24 months in 9.9% vs. 19.4% (p < 0.001), any bleeding at 24 months in 43.7% vs. 55.0% (p < 0.001), respectively.

Arterial hypertension

The goal of the **RADIANCE-HTN SOLO** [19] trial was to assess the safety and efficacy of renal denervation with the Paradise system (n=72) or a sham procedure consisting of renal angiography only (n=74) among patients with systolic and diastolic hypertension. A minimum of two sonications of 7 seconds each were delivered in the main branch of the right and left renal artery according to individual treatment plans developed on the basis of the pre-randomization computed tomography or magnetic resonance angiography. All patients underwent a 4-week period prior to randomization. Participants remained off antihypertensive medications until 2 months after randomization unless office blood pressure reached 180/110 mm Hg or home BP reached 170/105 mm Hg. Mean BP level during this period of trial was 143/93 mmHg. Between second and fifth month, patients with BP ≥135/85 mmHg were prescribed 5mg of amlodipine daily, standard dose of angiotensin converting enzyme inhibitor/angiotensin II receptor blocker and 12.5 mg/day of hydrochlorothiazide with dose increase of hydrochlorothiazide (up to 25 mg/day) and amlodipine (up to 10 mg/day) if necessary.

6 months after percentage of patients receiving antihypertensive medications was 65.2% vs. 84.5% (p = 0.008) with average number of antihypertensive medications 0.9 vs. 1.3 (p = 0.010). Change in daytime ambulatory systolic BP at 6 months was –18.1 mmHg in renal denervation group and 15.6 mm Hg in sham procedure group (between-group difference of –2.3 mm Hg, p = 0.24; further adjusted for number of antihypertensive medications: –4.3 mm Hg, p = 0.024). No serious adverse effects were registered among participants from both groups.

The results of this trial indicate that, renal denervation system resulted in a greater BP reduction at 2 months compared with a sham procedure without antihypertensive medications. By 6 months, nearly two thirds of patients required antihypertensive therapy even after renal denervation. However, the number and dose of medications required was lower compared with the sham arm. These results need to be replicated in a larger cohort with longer follow-up.

Small subcortical brain vessels impairment characterized by white matter hyperintensity according to magnetic resonance tomography is associated with reduced function in elderly patients with arterial hypertension. The **INFINTY** [20] study compared the effect of intensive ambulatory BP lowering (systolic ≤130 mm Hg; n = 99) with standard ambulatory BP lowering (systolic = 145 mm Hg; n = 100) on the white matter hyperintensity development, cognitive function, mobility function in patients with systolic arterial hypertension (150–170 mm Hg on ≥1 antihypertensive drug or >170 mm Hg on 0–1 antihypertensive drug) aged ≥75 years (average age 80 years).

Ambulatory systolic BP at 3 years was 130.9 mmHg versus 146.0 mmHg (p<0.001), white matter hyperintensity according to magnetic resonance tomography, was 0.29% and 0.48% (p = 0.03) in intensive and standard treatment, respectively. Groups did not change by change from baseline to end of study gait speed (p = 0.91) and study symbol digit modalities test (p = 0.29). Among six parameters of cognitive functioning, only sequential reaction time showed a difference that favored intensive therapy over standard therapy. Nonfatal cardiovascular events (MI, stroke, heart failure, arrythmia) were 4.1% in the intensive group vs. 17% in the standard group (p < 0.01) (HR 0.24 with 95% CI from 0.08 to 0.68; p<0.01). The frequency of falls and fainting did not differ significantly between groups.

According to study, lowering of BP is associated with a reduction in nonfatal cardiovascular events but does not affect cognitive function. Free years of follow-up may be not enough to evaluate functional status changes and results of the study do not contradict more intensive treatment in elderly patients with arterial hypertension.

Conclusion

Most important clinical studies data presented during scientific sessions of 68th American College of Cardiology American held in 2019 are presented in this article.

More detailed information is presented on the official website: https://www.acc.org.

New scientific information, obtained during well-planned and carefully performed randomized clinical trials will improve medical practice.

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