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ABSTRACT

As every year, the 68th American College of Cardiology (ACC) conference was held in New Orleans, Louisiana, from March 16 to 18. With carnival and jazz as the background, he convened the world cardiology again to promote knowledge by displaying a variety of scientific activities. More than 16,000 participants attended and 2,300 articles were received, many of which will undoubtedly change current clinical practice. It is also worth noting that the introduction of the guidelines for primary pretreatment of cardiovascular diseases emphasizes that acetylsalicylic acid is almost completely abandoned in primary pretreatment due to the lack of net profit.

We will briefly summarize some of the major scientific papers submitted:

1. Antithrombotic therapy after PCI for acute coronary syndrome or atrial fibrillation—Augustus test

2. Transcatheter aortic valve replacement and balloon dilatation in low-risk patients-partner 3 trial

3. Safety and effectiveness of STEMI femoral artery access: Safari STEMI trial

4. One month after drug-eluting stent implantation, clopidogrel monotherapy was compared with clopidogrel standard 12-month dual antiplatelet therapy. Stop DAPT 2 test

5. Results of a large-scale application based study using Smartwatch to identify atrial fibrillation: Apple heart research

Keywords: cardiology; meeting; summary

1. Antithrombotic therapy after PCI for acute coronary syndrome or atrial fibrillation—Augustus test

In patients with atrial fibrillation (AF) anticoagulation with coronary syndrome (ACS) or percutaneous coronary intervention (PCI), there are doubts about appropriate antithrombotic therapy[1].

Given the limited data on the use of apixaban in patients with atrial fibrillation and dual antiplatelet aggregation, the Augustus study was conducted to evaluate the effectiveness and safety in this regard. This is an open label, randomized controlled clinical trial involving 4,614 patients from 33 countries who have anticoagulant indications for atrial

fibrillation with ACS or PCI and need to be treated with P2Y12 inhibitors for at least 6 months[1,2]. Patients who banned dual antiplatelet therapy and those who needed vitamin K antagonists (AVK) for other reasons were excluded: Prosthetic valves, moderate or severe mitral stenosis.

The design was a 2×2 factor analysis. During the initial open period, patients were randomly divided into taking 5 mg apixaban anticoagulant twice a day (2.5 mg twice a day, 2–3 in selected patients) or AVK with a target INR between 2–3. Subsequently, each of these groups was assigned to another double-blind faze for 6 courses of aspirin or placebo[1,2]. The primary objective was safety: The presence of major bleeding (according to the international society for thrombophilia and hemophilia) or clinically relevant minor bleeding, while secondary (efficacy) targets included death/ hospitalization and death/ ischemic event complexes[1].

The average age was 70 years old, women accounted for 30%, and CHA2DS2-VASc was 3.9 ± 1.6. P2Y12 inhibitors were mostly (90%) treated with clopidogrel. Related to the type of event, about 60% of patients developed ACS (60% underwent PCI) and 40% underwent selective PCI.

The findings were published in the New England Journal of Medicine by Dr. Renato Lopes (MD, MHS, Duke University, North Carolina). Compared with placebo group (HR 1.89; 95% CI 1.59–2.24; P < 0.001)[1], the main goal of apixaban was 10.5%, compared with 14.7% in AVK group (HR 0.69; 95% CI 0.58–0.81; P < 0.001 for non-inferiority and superiority) and 16.1% in aspirin group. When comparing the four treatment branches, it was found that the combination of AVK + aspirina had the most bleeding (18.7%), while apixaban + placebo (7.3%) had the least bleeding.

With regard to secondary goals, the incidence of composite death or hospitalization was lower in patients with apixaban than in patients treated with AVK (23.5% vs 27.4%; HR 0.83; 95% CI, 0.74–0.93; P = 0.002), while there was no significant difference between aspirin and placebo. The

comparison of AVK versus apixaban and aspirin with placebo showed that the incidence of ischemic events was similar[1].

The authors concluded that among patients with AF, ACS, or PCI recently treated with P2Y12 inhibitors, apixaban antithrombotic regimen (without aspirin) resulted in less bleeding and hospitalization and no significant difference in the incidence of ischemic events compared with patients with AVK, aspirin, or both[1].

After consultation, Dr. Lopez said, "Due to concerns about massive bleeding, there are problems with the appropriate treatment of patients with AF and ACS and / or PCI. The results of this study provide additional information for doctors who treat these high-risk patients."[3]

2. Transcatheter aortic valve replacement and balloon dilator valve in low-risk patients-partner 3 trial

Transcatheter aortic valve implantation (TAVI) has been positioned as an alternative to surgical aortic valve replacement (TAVR) for patients with severe aortic stenosis (SAS), who have severe, high and extreme surgical risks[4]. In randomized studies, TAVI was higher or not lower than TAVR and had a large number of records, including self-interpretation and balloon dilatation[4]. For patients with low surgical risk, a note study was published in 2015, which randomly divided SAS patients into TAVI (139 patients) or TAVR (135 patients) and coronary artery disease without intervention (5 patients)[5]. Among them, 82% of patients had a low risk of surgery (according to the association of Thoracic Surgeons [STS-PROM] score mortality predictor, the mortality was less than 4%). At 5-year follow-up, there was no significant difference in the primary endpoint of all-cause death, stroke and infarction (39.2% for TAVI vs. 35.8% for surgery, p = 0.78)[6].

Despite this result, the guidelines still recommend the use of TAVR in patients with low surgical

risk[4]. On March 17, Dr. Martin Leon (MD, Presbyterian Hospital, New York) and simulti published part 3 of the study in the New England Journal of Medicine[7] to expand the evidence for the use of TAVI in this group.

This multicenter, randomized, 1:1 study compared 1000 low-risk SAS patients with TAVR using biological valves[7]. Low clinical risk was defined as STS-PROM < 4%. Patients with clinically fragile, bicuspid or monocuspid aortic valves or other patients who may increase the risk of surgical complications (severe aortic insufficiency) were excluded. Of the 1000 patients randomly selected, 50 were not included in the analysis, and most of them refused treatment or chose another non-research center. 7.9% of TAVI patients and 26.4% of TAVR patients underwent another operation[7].

The average age was 73 years old (male 69%), and the average STS score was 1.9% (7.8%). The primario target (including all-cause death, CVA or annual re-hospitalization) was 8.5% in grupo TAVI and 15.1% in TAVR group (HR 0.54; 95% CI, 0.37–0.79; P = 0.001), showing the perioperative period of TAVI[7,8]. Through a separate analysis of the main target components, all of these components have TAVI tendency[7].

Among secondary objectives, the results of two to 30 days showed that the TAVI group[7,8] had lower ACV rate (0.6% vs 2.4%; P = 0.02), ACV and mortality (1.0% vs 3.3%; P = 0.01), and new onset AF (5.0% vs 39.5%; P < 0.001). The annual mortality or ACV disability rate was 1% in the TAVI group and 2.9% in the surgical group (HR 0.34; 95% CI, 0.12–0.97)[7].

The hospitalization rate of TAVI implants was also lower than that of surgery (3 days vs 7 days, P < 0.001)[7], and NYHA functional grade, 6 minute caminata test distance and Kansas City heart disease quality of life questionnaire score[8] improved faster.

There was no significant difference between the two groups in terms of 30 days safety objectives (major vascular complications, permanent pacemaker implantation, moderate and severe paravalvular leakage or coronary artery occlusion). However, the rate of major or life-threatening bleeding was 3.6% in the TAVI group and 24.5% in the surgical group (HR 0.12; 95% CI, 0.07–0.21)[7].

It should be noted that the incidence of complete left bundle branch block was 32.7% in TAVI group and 8.0% in operation group (HR 3.43; 95% CI, 2.32–5.08), and the rate of slight valve leakage was also conducive to operation (29.4% vs 2.1%)[7,8].

As the main limitation of this study, the author mentioned that it only reflected the results of one year and did not evaluate the long-term deterioration of valve structure. "The final conclusion on the advantages and disadvantages of lvta compared with surgery depends on long-term follow-up," they mentioned at the end of the report[8].

To highlight the relevance of the post presentation study, Dr. Braunwald mentioned, "This is a historic moment that everyone here should recognize. (...) I will tell our grandchildren that while we were there, we made amazing progress in caring for patients with aortic stenosis"[9].

3. Safety and efficacy of percutaneous coronary intervention for ST segment elevation myocardial infarction: Safari STEMI trial

Percutaneous coronary intervention (PCI) is the first choice for ST segment elevation acute myocardial infarction (STEMI). The latest guidelines take the radial artery pathway as the standard technology for coronary angiography and PCI. According to the results of the matrix study, there is level I evidence, in which the radial pathway is associated with reducing the risk of puncture bleeding, vascular complications and blood transfusion needs, as well as reducing mortality, thus strengthening the results of the competitive and rifle steacs study[10,11].

Considering that many intervention centers in the United States and Canada prefer femoral artery intubation (despite good evidence of radial artery intubation), the purpose of the safari STEMI study was to compare two intubations using new drug treatments and techniques (not previously included) in patients undergoing STEMI PCI[12].

Safari STEMI was a randomized, open, parallel allocation and blind evaluation study with a follow-up of 30 days. The primary goal was all-cause mortality, and secondary goals included CVA, reinfarction, stent thrombosis, or bleeding. 2292 STEMI patients (mean age 62 years, body mass index 28.2, female 22%, diabetic cos 17%) with symptom onset time < 12 hours from five medical centers in Canada were included in PCI. 1136 patients were randomly divided into radial approach and 1156 femoral approach. All patients received 160 mg aspirin, P2Y12 inhibitor load and 60 IU/kg (up to 4000 IU) of undivided heparin. Patients who underwent fibrinolysis, oral anticoagulant and previous myocardial revascularization surgery[12–14] were excluded.

It should be noted that in both groups, most patients were treated with bivalirudi sodium during surgery and then ticagrel; 68.2% in femoral artery group and 5.5% in radius group. The crossover rates of radius and femur were 8.1% and 2.3%, respectively. It is unclear how many contacts were made under ultrasound guidance using micro smear kits[12,13,15].

The researchers initially planned to include 4,884 patients, but the study ended early due to ineffectiveness, and there was no difference in the main goal (all-cause mortality within 30 days: 1.5% in radius group and 1.3% in femur group (P = 0.69). There was also no difference in secondary targets, namely reinfarction (1.8% radius vs 1.6% femoral artery, P=0.83), ACV (1.0% vs 0.4% P = 0.12), and massive hemorrhage defined by TIMI and BARC (1.1% vs 1.3% P = 0.74). They concluded that in STEMI patients undergoing primary PCI, the radial pathway is not higher than the femoral pathway,

and appropriately trained surgeons should be able to use any of these pathways to achieve similar results[12–15].

Because the visit website sometimes needs to be changed during the operation, Michel Le May (M.D., Institute of Cardiology, Okawa University, Cana Da, FACC), the speaker of this paper, said, "I think it is important that the medical training program emphasizes the need to be proficient in the radial artery pathway of the femur, and may be under trained in performing one task, while constantly emphasizing the other task may lead to an increase in complications[14]".

Claire Duvernoy (University of Michigan), a person trained in cross-femoral surgery, calls these results "sedatives". She chose the radial approach in the elective patients, but when the opportunity was critical, such as STEMI cases, her first instinct was to use the femoral approach. Sunil Rao (Duke University), an advocate of wireless access, said, "Although this low-power trial did not show the difference between radius and femur, it is unclear whether really good femoral approach observance results can be obtained in clinical practice". He also stressed that the early interruption of the study prevented us from reaching clear conclusions. Duvernoy mentioned to the media that the use of bivalirudin and closure devices in his hospital is not a standard practice, so inferring the results will be a challenge[16].

During the presentation, Le May showed the latest meta-analysis data, including Safari STEMI results: Patients with STEMI treated via radial artery had a lower risk of mortality, but the relative benefit was close to the unit (RR 0.78; 95% CI 0.61–0.99)[16].

4. Dual antiplatelet therapy 1 month after clopidogrel alone and clopidogrel alone Standard 12-month dual antiplatelet therapy with clopidogrel after drugeluting stent implantation. Stop DAPT 2 test

Antiplatelet therapy after cardiovascular intervention is a subject of current research, which is, inter Alia, why the most advanced coronary stents have a lower risk of thrombosis than previous stents. In addition, the risk of dual antiplatelet associated bleeding (DAPT) permanently increases with the continuation of treatment, and its mortality is comparable to new myocardial infarction (MI). The STOP-DAPT 2[17] study was proposed by Dr. Yukio Watanabe (MD, Kyoto University, Japan) on March 18 2019, but the results have not been published. This is a randomized, multicenter joint study conducted in 90 centers in Japan. Its main purpose is to demonstrate that after the implantation of the latest generation everolimus eluting stent, it is first treated with DAPT for one month, then treated with clopidogrel monotherapy, and then combined with aspirin and clopidogrel for 12 months.

The results given correspond to the preliminary analysis of one-year non-inferiority. The primary endpoint was the composite of cardiovascular death, myocardial infarction, stent thrombosis, CVA and bleeding, according to the thrombolysis score of myocardial infarction (TIMI). Secondary end objectives included independent analysis of the above ischemic and bleeding events. Patients with anticoagulants and a history of intracranial hemorrhage were excluded. Of the 6,504 patients who met the inclusion criteria, 3,045 patients were randomly divided into one of two treatment branches, of which 36 patients withdrew from the study. The final analysis included a total of 3,009 patients: 1,500 received DAPT for one month and 1,509 received DAPT for 12 months. The average age is 68, and only 21% of the female Nina population. 39% of the patients were diabetic and 62% had stable ischemic heart disease. 83% of patients used radial approach and 97% of patients used intravascular ima gene technology for angioplasty. According to credo Kyoto thrombotic risk score and credo Kyoto bleeding risk score, more than 90% of patients are at risk of thrombosis and bleeding.

The authors found that within one month, the net benefit of DAPT compared with Tada was 2.4% to 3.7% (non inferiority p value<0.001, superiority p value 0.04). Independent analysis of ischemic and bleeding events showed that the significant difference in combined results was mainly due to the reduction of bleeding events. However, in the one-year analysis of the second chemical event endpoint, one month of DAPT non-deterioration persisted (2.0% vs 2.5%, P non-deterioration dad=0.005). Primary and secondary TIMI bleeding was significantly reduced in the shortened DAPT group (0.4% vs 1.5%, non-inferior p-dad=0.002, dominant p-value=0.004). "In conclusion, ladies and gentlemen, the one-month DAPT followed by clopidogrel monotherapy provides a net clinical benefit for isquia and bleeding events (...) After the implantation of the latest generation of everolimus eluting stents," Watanabe said. "This benefit is due to a significant reduction in bleeding without an increase in ischemic events[18]".

The main limitation of this study is the low or moderate risk of ischemia in the study population, which makes it impossible for high-risk patients to obtain a prognosis. On the other hand, optimizing coronary intervention through intravascular imaging reduces the risk of stent thrombosis, but in our environment, this is a limited use strategy. Japanese patients also have a low risk of ischemia compared to European and American populations, which is emphasized in the report[18,19]. In order to understand the results of this work more widely, we look forward to its publication.

5. Results of a large-scale application based study using Smartwatch to identify atrial fibrillation: Apple heart research

The preliminary data[20] of this study was provided by Dr. Mintu Turakhia (MA, MD, Stanford University), which is the most expected data of con greso. With the popularity of Apple Watch and other portable devices, applications for detecting heart rhythm have been designed to identify common arrhythmias, especially atrial fibrillation. To this end, a new prospective single arm study was designed, involving 419,297 U.S. participants from November 2017 to July 2018. Includes iPhone 5 or later, Apple Watch series 1 or later, and standards aged ≥ 22. Patients with a history of atrial fibrillation, atrial flutter or anticoagulant therapy at the time of recruitment were excluded.

The primary objective was to measure the percentage of participants with irregular pulse detected by Apple Watch who were diagnosed with atrial fibrillation by patches recording ECG trajectories. As a research goal, we propose to use Apple Watch to characterize the correlation between irregular pulses and synchronously recorded ECG, and estimate the tasa in contact with health professionals after detecting irregular pulses.

Individuals who were interested in downloading the application and met the inclusion criteria were invited to participate in the study. The irregular pulse recognition algorithm uses the waveform of optical plethysmography to create tacograma (function of heart rate and time). If tacogram meets the irregularity criteria, prospective screening is performed to confirm the findings. In the case of five consecutive irregular heartbeats, through the application, participants will be informed of the premonition of irregular pulse, contact professionals through telemedicine, and be required to see a health center, or stick a patch that can record ECG to show the presence of atrial fibrillation (monitoring for at least 7 days). In this case, virtual access is planned.

Of the overall cohort, 42% were women (177,087), with a clear predominance of young participants (52%–219,179–between 22 and 39 years of age) of white race (68%–286,190–). A total of 2,161 participants (0.52%) were notified of the application, 21% of whom were women (461) with a predominance of 65 years of age (36%–775–). A total of 945 participants (44%) underwent virtual consultation and 30% were referred to the emergency department for associated symptoms. The remaining 70% had patch ECG recording placed, but only 450 were returned and included in the analysis (23% women). $CHA_2DS_2VASc \geq 2$ was 13% in the overall cohort (55,277 participants), increasing frankly to 33% in those who received irregular rhythm notification and in the ECG patch group (38%). The same behavior was observed for individual risk factors such as obesity, arterial hypertension, and diabetes mellitus.

In the 8-month monitoring results, the reporting rate of irregular pulso was very low, 0.52% (2,161/419,297 participants), which was significantly related to age (the reporting rate over 65 years old was 3.2%, 775/24,626 participants). When the ECGs of individuals with irregular pulse notification by the application were analyzed, only 34% (153/450) were confirmed to have AF, which implies that 66% had "false alarms". The positive predictive values of ECG for the total cohort of Che atrial fibrillation were 0.71 and 0.84, respectively. As for the duration of AF (considered by the device when it was 30 seconds), 89% of the episodes lasted 1 hour with 25.5% lasting 24 hours. Another noteworthy aspect is that among patients with reported irregular pulse, 90 days of guidance (1,376/2,161, 64%) was completed, and 57% (787/1,376 pairs of drugs) contacted health professionals outside the application. In these cases, various behaviors were taken, such as starting new treatment (28%), referring experts (33%) and additional studies (36%). The reported adverse events were very low (1,038/419,297) and mainly unrelated to application (1,022/1,038).

These limitations were highlighted: After re-

porting, mayor abandoned expectations (64%) and provided fewer ECG patches than planned, which reduced the accuracy and actual design of the study, in which the data were reported by the participants themselves[21]. The registration target of 500,000 participants over 75,000 years of age[22] has also not been achieved.

With regard to the fact that only 34% of people were confirmed, Dr. Turakhia said, "This does not mean that 66% of people do not have atrial fibrillation. It just means that the FA may not have been there." With regard to the new virtual experience, he stressed, "this study improves our understanding of how applications and portable technology work in the real world and to what extent it can detect prolonged atrial fibrillation. The low reporting rate of arrhythmias is an important finding because people are worried about over reporting, and we can see what happens when participants are notified"[23].

This virtual study is the first step in laying the foundation for future research, which will find suitable portable technologies to support cardiovascular health. "This really represents a paradigm shift in the way clinical research is conducted," Turakhia said.

Conflict of interest

The authors declare no conflict of interest.

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