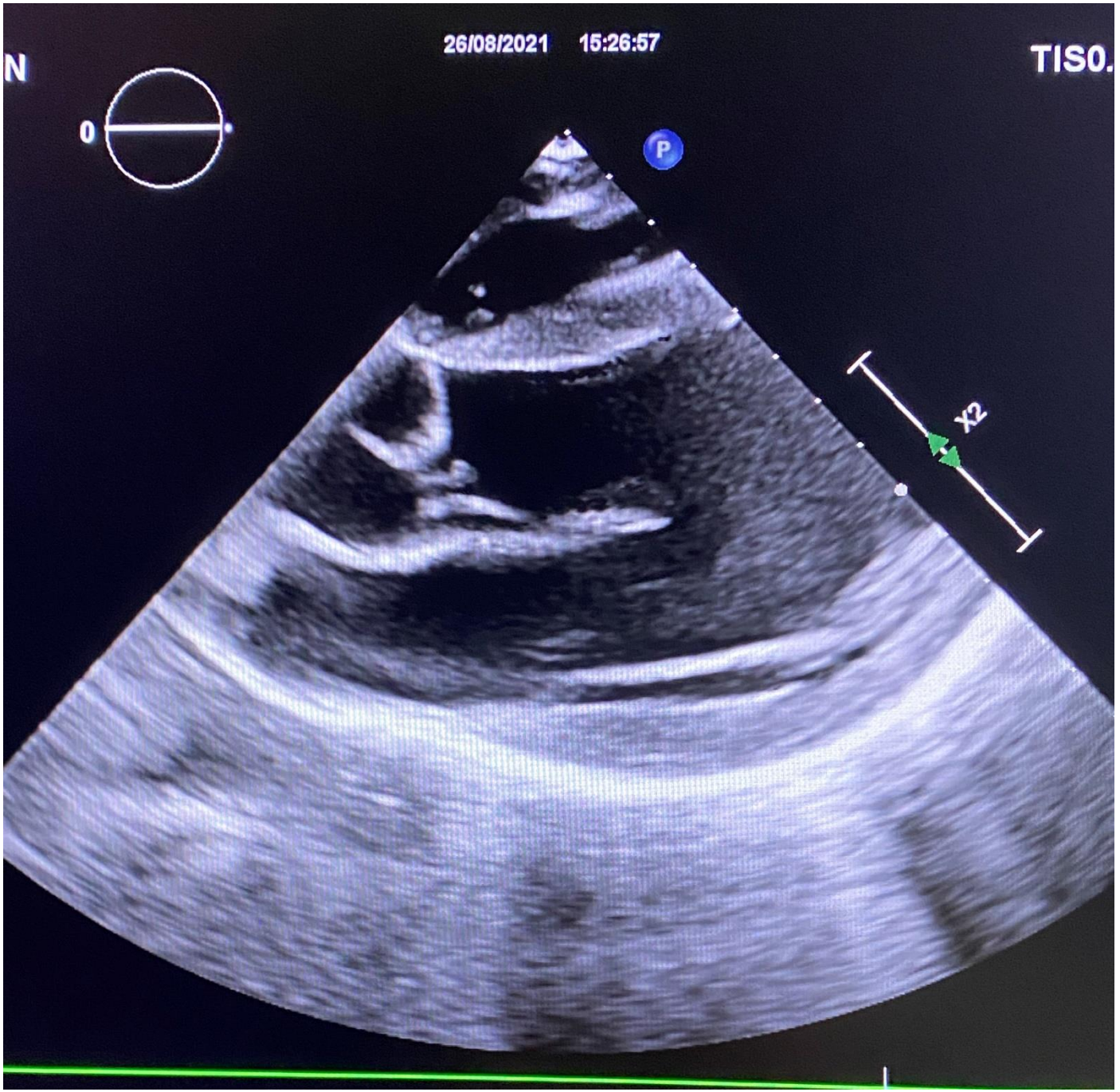
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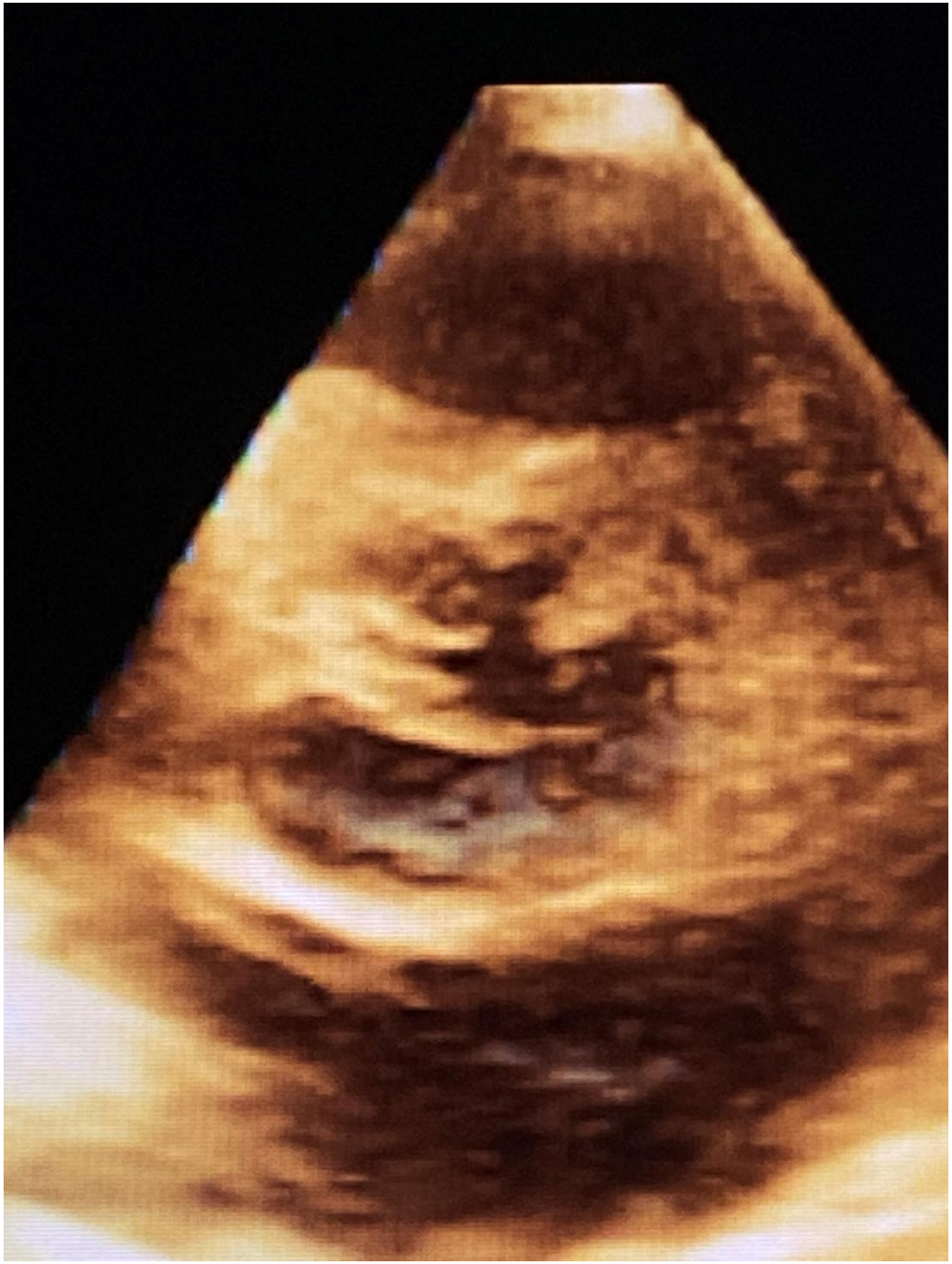

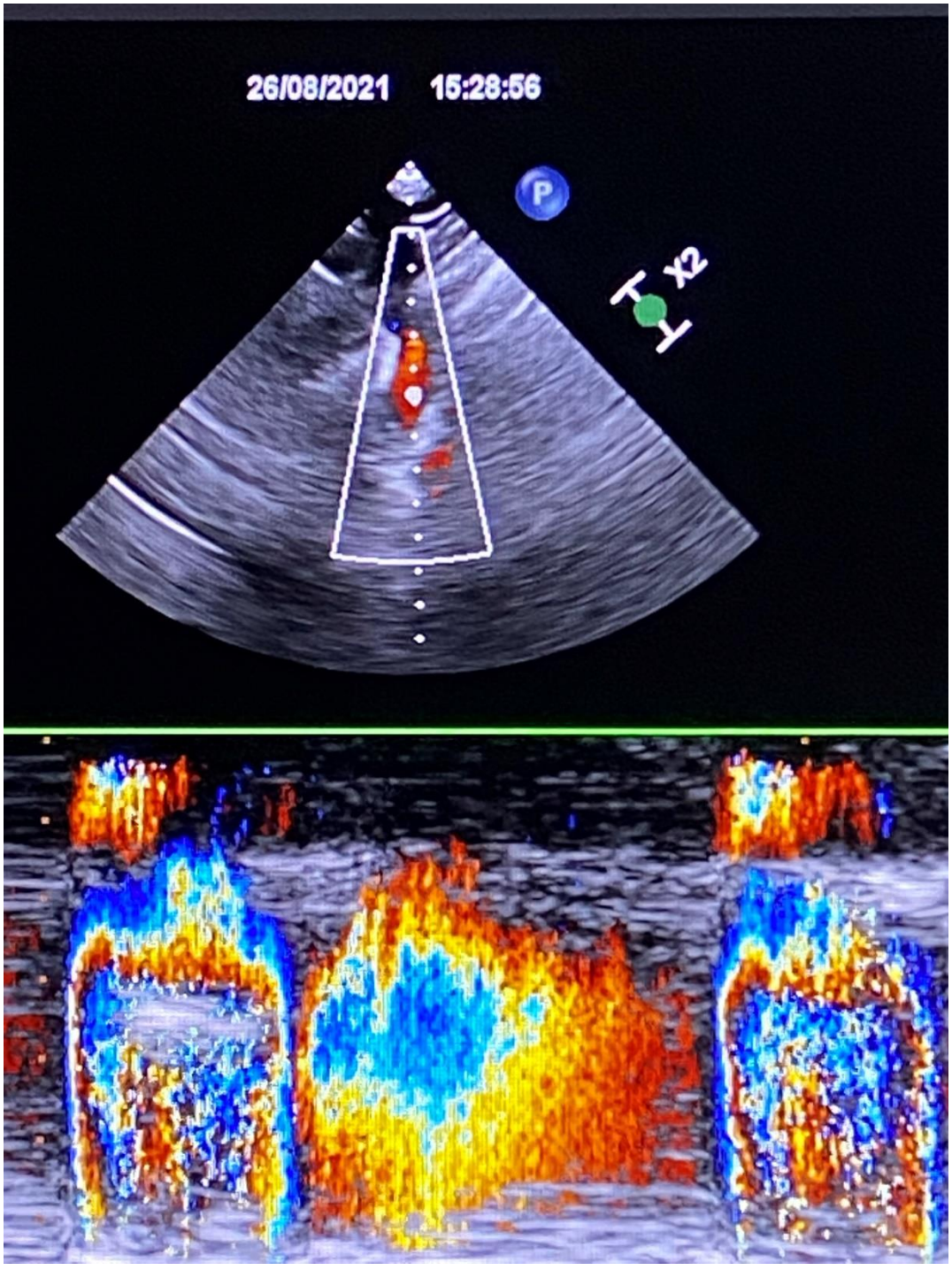
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APAF-CRT: Does Ablation Plus CRT Reduce Mortality in Permanent AFib Patients With Narrow QRS?

"We hypothesize that the observed benefit was due to the combination of the strict rate control and rate regularization achieved by AV junction ablation, together with biventricular pacing which counteracted the adverse effects of right ventricular pacing," said principal investigator **Michele Brignole, MD**. "The improvement in survival shown by the APAF-CRT trial supports ablation plus CRT as a first-line therapy in patients with permanent AFib, narrow QRS and previous hospitalization for heart failure."

Conclusions

- Rate-control by Ablation+CRT was superior to rate-control by pharmacological therapy in reducing mortality in patients with permanent AF and narrow QRS.
- The benefit was observed in patients with preserved EF with no interaction between patients with EF >35% and those ≤35%.
- The benefit was due to the combination of the strict rate control and rate regularization achieved by AV junction ablation together with biventricular pacing, which counteracted the adverse effects of right ventricular pacing.
- APAF-CRT trial results support Ablation+CRT as a first line therapy in patients with permanent AF and narrow QRS who were hospitalized for HF.

2021 ESC/EACTS Valvular Heart Disease Guidelines: Key Points

Aug 28, 2021 | Debabrata Mukherjee, MD, FACC

Authors:	Vahanian A, Beyersdorf F, Praz F, et al.
Citation:	2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease: Developed by the Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J* 2021;Aug 28: [Epub ahead of print].

The following are key points to remember from the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) about the 2021 Guidelines for the Management of Valvular Heart Disease (VHD):

1. Meticulous evaluation of the patient's history and symptomatic status, as well as proper physical examination, are crucial for the diagnosis and management of VHD.
2. Echocardiography is the key technique to diagnose VHD and assess its severity and prognosis. Other noninvasive investigations such as cardiac magnetic resonance, cardiac computed tomography, fluoroscopy, and biomarkers provide important additional information in selected patients. Stress testing should be widely used in asymptomatic patients. Invasive investigation, beyond preoperative coronary angiography, is limited to situations where noninvasive evaluation is inconclusive.
3. Decision making in elderly patients requires the integration of multiple parameters, including estimation of life expectancy and anticipated quality of life, evaluation of comorbidities, and general condition (including frailty). Informed patient expectations and values are an important part of the decision-making process.

4. Heart Valve Centers with multidisciplinary Heart Teams, Heart Valve Clinics, comprehensive equipment, and sufficient volumes of procedures are required to deliver high-quality care and provide adequate training.
5. In patients with atrial fibrillation, nonvitamin K antagonist oral anticoagulants (NOACs) are contraindicated in patients with clinically significant mitral stenosis or mechanical valves. For stroke prevention in patients who are eligible for oral anticoagulation, NOACs are recommended in preference to VKAs in patients with aortic stenosis, aortic and mitral regurgitation, or aortic bioprostheses >3 months after implantation.
6. Selection of the most appropriate mode of intervention for severe aortic stenosis by the Heart Team should take into account clinical characteristics (age and estimated life expectancy, general condition), anatomical characteristics, the relative risks of surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI), the feasibility of transfemoral TAVI, local experience and outcome data, as well as informed patient preference.
7. Surgical mitral valve repair is the preferred method of treatment in primary mitral regurgitation (MR) if a durable repair can be achieved. Transcatheter edge-to-edge repair (TEER) is a safe but less efficacious alternative that may be considered in patients with contraindications for surgery or high operative risk.
8. On the other hand, in patients with severe secondary MR, guideline-directed medical therapy (including ardiac resynchronization therapy if indicated) should be the first step. If the patient remains symptomatic, mitral surgery is recommended concomitantly in patients with an indication for coronary artery bypass grafting or other cardiac surgery. Isolated valve surgery may be considered in selected patients. TEER should be considered in patients not eligible for surgery and fulfilling criteria indicating an increased chance of responding to the treatment. Circulatory support devices, cardiac transplantation, or palliative care should be considered as an alternative in patients with end-stage left ventricular and/or right ventricular (RV) failure.
9. Tricuspid regurgitation should be liberally treated at the time of left-sided valve surgery. Isolated surgery of severe secondary tricuspid regurgitation (with or without previous left-sided valve surgery) requires comprehensive assessment of the underlying disease, pulmonary hemodynamics, and RV function.

9. Tricuspid regurgitation should be liberally treated at the time of left-sided valve surgery. Isolated surgery of severe secondary tricuspid regurgitation (with or without previous left-sided valve surgery) requires comprehensive assessment of the underlying disease, pulmonary hemodynamics, and RV function.

10. The choice between a mechanical prosthesis and a bioprosthesis should be patient-centerd and multifactorial based on patient characteristics, the indication for lifelong anticoagulation, the potential and risks of a re-intervention, and the informed patient preference. Clinical assessment of prosthetic valves should be performed yearly and as soon as possible if new cardiac symptoms occur.

Valvole del cuore, quando, come e perché intervenire

di Federico Mereta

Secondo le nuove linee guida della Società Europea di Cardiologia per affrontare le malattie valvolari è fondamentale affidarsi a centri che abbiano esperienza. Serve un team di esperti per scegliere, caso per caso, se ricorrere al bisturi o al trattamento non invasivo

01 SETTEMBRE 2021

3 MINUTI DI LETTURA

Poco più di una persona su dieci, superata la soglia dei 75 anni, può presentare una malattia di una o più valvole del cuore. e dopo i 65 anni i rischi aumentano, stando alle stime delle ricerche internazionali.

In alcuni casi, specie se il quadro non è particolarmente grave, possono non manifestarsi disturbi, anche se la circolazione del sangue non è ottimale. In altri si possono avere sintomi diversi, dalle palpitazioni fino all'affanno e alla perdita di coscienza. O addirittura dolori che possono far pensare ad un infarto. Poi lo specialista scopre che una valvola non "lascia passare normalmente il sangue al suo interno quando questo viene spinto (in questo caso si parla di stenosi) o/e non si chiude perfettamente al momento giusto, consentendo un rigurgito di sangue verso l'indietro (insufficienza).

In tutti i casi i casi il quadro va individuato e poi trattato, caso per caso, sempre ricordando che a volte in una stessa valvola ci possono essere insufficienza e stenosi e che queste patologie possono manifestarsi in più valvole contemporaneamente.

Ma come occorre comportarsi? Per dare una risposta arrivano le linee guida della **Società Europea di Cardiologia (Esc)** e dell'**Associazione Europea per la Chirurgia Cardio-Toracica (Eacts)**, pubblicate su *European Heart Journal*.

Secondo le nuove linee guida il primo passo fondamentale è sottoporsi ad una visita cardiologica. L'esame clinico, secondo le linee guida, è un fattore fondamentale per individuare il sospetto di una patologia valvolare. Poi si passa ad esami diagnostici più fini, privilegiando test che non siano invasivi a partite dall'ecocardiografia per poi approfondire con altri esami, su consiglio dei curanti.

Sul fronte delle cure, il fattore chiave è affadarsi a centri che abbiano un elevato volume di trattamenti e che possano affrontare la situazione identificando tempi e modi del trattamento grazie ad un'unità specializzata (**Heart Team**) che comprenda cardiologi clinici e interventisti, cardiochirurghi, specialisti di imaging, anestesisti cardiovascolari e infermieri,. Fondamentale, caso per caso, è tenere sempre presenti assieme il quadro clinico e la situazione anatomica, oltre alla preferenza del paziente.

IL GUSTO

La caprese divent

Si arriva così alla cura. Stando a quanto riporta la comunicazione dell'Esc gli interventi (percutanei o chirurgici) sono indicati nei pazienti sintomatici se vi è un beneficio atteso.

Il processo decisionale nei pazienti asintomatici deve soppesare il rischio dell'intervento rispetto alla storia naturale attesa della patologia: quando si prevede una rapida progressione dei sintomi, l'intervento può essere giustificato se il rischio procedurale è basso. Nei pazienti anziani, le decisioni dovrebbero considerare l'impatto stimato del trattamento sull'aspettativa di vita e sulla qualità della vita. Insomma: anche il paziente ha un ruolo importante nella scelta dell'approccio.

Secondo il presidente della task force Eacts, **Friedhelm Beyersdorf** dell'*Università di Friburgo*, "i pazienti e le loro famiglie dovrebbero essere accuratamente informati e assistiti nelle loro scelte. Il sollievo dei sintomi da solo può giustificare l'intervento se è una priorità per il paziente. Tuttavia, il trattamento è considerato inutile quando non si prevede che prolunghi la vita o allevi i sintomi".

IL GUSTO

La caprese diventa gelato: stick di mozzarella e sorbetto

Age- and BP-Stratified Effects of BP-Lowering Pharmacotherapy

Aug 28, 2021

Authors:	The Blood Pressure Lowering Treatment Trialists' Collaboration.
Citation:	Age-Stratified and Blood-Pressure-Stratified Effects of Blood-Pressure-Lowering Pharmacotherapy for the Prevention of Cardiovascular Disease and Death: An Individual Participant-Level Data Meta-Analysis. *Lancet* 2021;Aug 26:[Epub ahead of print].
Summary By:	Elizabeth A. Jackson, MD, FACC

Quick Takes

- Pharmacological BP lowering is effective for older adults and should be considered for management of elevated BP irrespective of age.
- Absolute CV risk reduction is significant among older age groups.
- No evidence of adverse mortality associated with pharmacological BP lowering was observed for any age group.

Study Questions:

Is pharmacological blood pressure (BP) lowering associated with cardiovascular (CV) outcomes among older adults?

Methods:

This meta-analysis included participants from randomized clinical trials which compared pharmacological BP lowering versus placebo or other classes of BP-lowering medications or between more versus less intensive treatment strategies. Included trials had to have at least 1,000 person-years of follow-up in each treatment group. Participants with a previous history of heart failure were excluded. Data were obtained from the Blood Pressure Lowering Treatment Trialists' Collaboration. Patient-level data were grouped by age using five groups (<55 years, 55-64, 65-74, 75-84, and ≥85 years). Baseline systolic BP was grouped into seven categories (from <120 mm Hg to ≥170 mg Hg). Baseline diastolic BP was grouped into six categories (from <70 mm Hg to ≥110 mm Hg). The primary outcome was a composite of fatal or nonfatal stroke, fatal or nonfatal myocardial infarction or ischemic heart disease, or heart failure causing death or requiring hospital admission. The secondary outcomes were all-cause death and each component of the primary outcome.

Results:

A total of 358,707 participants from 51 randomized clinical trials were included in this meta-analysis. The age of participants at randomization ranged from 21 years to 105 years (median 65 years [interquartile range, 59–75 years]), 128,506 (35.8%) 65–74 years, 54,016 (15.1%) 75–84 years, and 4,788 (1.3%) ≥85 years. The hazard ratios for the risk of major CV events per 5 mm Hg reduction in systolic BP for each age group were 0.82 (95% confidence interval, 0.76–0.88) in individuals <55 years, 0.91 (0.88–0.95) in those aged 55–64 years, 0.91 (0.88–0.95) in those aged 65–74 years, 0.91 (0.87–0.96) in those aged 75–84 years, and 0.99 (0.87–1.12) in those aged ≥85 years. Similar patterns of proportional risk reductions were observed for a 3 mm Hg reduction in diastolic BP. Absolute risk reductions for major CV events varied by age and were larger in older groups.

Conclusions:

The investigators concluded that pharmacological BP reduction is effective into old age, with no evidence that relative risk reductions for prevention of major CV events vary by systolic or diastolic BP levels at randomization, down to <120/70 mm Hg. Pharmacological BP reduction should, therefore, be considered an important treatment option regardless of age, with the removal of age-related BP thresholds from international guidelines.

Perspective:

These data support the use of antihypertensive medications to treat BP, even among older adults. Furthermore, this meta-analysis demonstrated significant absolute risk reduction in CV events associated with pharmacologic BP treatment.

DECAAF II: Image-Guided Fibrosis Ablation Compared With PVI Alone in Treating AFib

Aug 28, 2021

ACC News Story

Image-guided fibrosis ablation in addition to pulmonary vein isolation (PVI) did not improve ablation success rates in patients with persistent atrial fibrillation (AFib) compared with PVI alone, according to investigators presenting findings from the DECAAF II trial at ESC Congress 2021. However, as-treated analyses showed that covering low-grade atrial fibrosis with ablation lesions did lead to a significant reduction in atrial arrhythmia recurrence.

The trial enrolled 843 patients (median age 62 years, 78.8% men) with persistent AFib from 44 centers around the world. Participants were randomized to receive either PVI plus imaging-guided fibrosis ablation (intervention group) or PVI alone. All patients underwent late gadolinium enhancement (LGE)-MRI at baseline prior to ablation and then approximately three months after. The baseline images were used during the procedure in the intervention group to guide ablation of fibrotic tissue. Operators were instructed to either cover or encircle the green areas on the images (i.e., the fibrotic tissue), in addition to PVI. Operators in the control group were instructed to only encircle the pulmonary veins, without adding additional lesions. The three-month MRI evaluated the formation of lesions secondary to ablation. The primary endpoint was atrial arrhythmia recurrence for 12 to 18 months.

Overall results found baseline fibrosis was predictive of AFib ablation outcomes, especially at higher fibrosis levels – findings that confirmed the results of the initial DECAAF study. In the intention-to-treat analysis, no statistically significant difference was observed in the primary endpoint between groups in the total study population. Atrial arrhythmia recurrence occurred in 43% of patients (n=175) in the intervention group and 46.1% of patients (n=188) in the PVI-only group.

Subgroup analyses suggested a trend towards a lower rate of atrial arrhythmia recurrence in the intervention group for patients with stage I or II fibrosis at baseline. As-treated analyses examining atrial arrhythmia recurrence according to the proportion of targeted and covered fibrosis (as assessed by the three-month MRI) found a significant benefit of substrate ablation in patients with stage I or II fibrosis at baseline. However, researchers observed no benefit of image-guided fibrosis ablation on atrial arrhythmia recurrence in patients with stage III or IV stage fibrosis at baseline. They also noted that the rate of complications, including post-ablation stroke, was higher in the image-guided ablation group but was mainly driven by patients with high levels of fibrosis at baseline.

"The results suggest that targeting atrial fibrosis in AFib patients with low levels of fibrotic disease (less than 20%) may help improve ablation outcomes," said principal investigator **Nassir Marrouche, MD**. "In addition, the findings indicate that PVI should remain the mainstream ablation strategy in AFib patients with high levels of fibrosis (more than 20%)."

DECAAF II: Summary

In patients with persistent AF:

- Intention to treat analysis shows that *fibrosis-guided* ablation was not superior to conventional PVI in reducing atrial arrhythmia recurrence
- There was an increased number of adverse events with *fibrosis-guided* ablation driven by advanced stages of fibrosis
- As-treated analyses suggest more successful fibrosis coverage/encirclement might reduce recurrence for early stages of fibrosis
- More advanced fibrosis was associated with altered ablation lesion formation

DECAAF II: Conclusion

In patients with persistent AF:

- Determining left **atrial fibrosis** may support a new **individualized approach** toward treating persistent AF patients with **early stage** of atrial disease
- **PVI** remains the mainstream ablation approach especially in patients with **advanced stages** of atrial fibrosis

Finerenone in Reducing Cardiovascular Mortality and Morbidity in Diabetic Kidney Disease - FIGARO-DKD

Aug 28, 2021

Author/Summarized by Author:	Dharam J. Kumbhani, MD, SM, FACC
Summary Reviewer:	Deepak L. Bhatt, MD, MPH, FACC
Trial Sponsor:	Bayer
Date Presented:	08/28/2021
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Date Updated:	08/28/2021
Original Posted Date:	08/28/2021

References

Contribution To Literature:

The FIGARO-DKD trial showed that finerenone has salutary effects on CV outcomes among patients with T2DM and CKD, who were on a background of maximal RAS blockade therapy, primarily due to a reduction in hospitalization for HF.

Description:

The goal of the trial was to assess the safety and efficacy of finerenone in reducing cardiovascular (CV) events among patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD).

Study Design

Eligible patients were randomized in a 1:1 fashion to either finerenone (n = 3,686) or placebo (n = 3,666). Patients with an estimated glomerular filtration rate (eGFR) of 25-60 ml/min/1.73 m^2 at the screening visit received an initial dose of 10 mg once daily, and those with an eGFR of ≥60 at the screening visit received an initial dose of 20 mg once daily. An increase in the dose from 10 to 20 mg once daily was encouraged after 1 month, provided the serum potassium level was ≤4.8 mmol/L and the eGFR was stable.

- Total screened: 19,381
- Total number of enrollees: 7,352
- Duration of follow-up: 3.4 years
- Mean patient age: 64.1 years
- Percentage female: 31%

Inclusion criteria:

- Age ≥18 years
- T2DM
- eGFR between 25 and 90 ml/min/1.73 m^2, moderately elevated albuminuria (urine albumin-to-creatinine ratio [UACR] between 30-300 mg/g); or severe albuminuria (UACR 300-5000 mg/g) an eGFR >60
- Maximal tolerated renin–angiotensin system (RAS) blockers
- Serum potassium ≤4.8 mmol/L

Exclusion criteria:

- Heart failure with reduced ejection fraction (HFrEF) with New York Heart Association (NYHA) class II-IV
- Uncontrolled hypertension

Other salient features/characteristics:

- Median glycated hemoglobin (HbA1c): 7.7%
- Mean systolic blood pressure: 136 mm Hg
- Mean eGFR: 67.8 ml/min/1.73 m^2
- Mean serum potassium: 4.3 mmol/L
- Diuretic: 48%, statin: 71%, SGLT2 inhibitor: 8%

Principal Findings:

The primary composite outcome of CV death, myocardial infarction (MI), stroke, hospitalization for HF, for finerenone vs. placebo, was 12.4% vs. 14.2% (hazard ratio [HR] 0.87, 95% confidence interval [CI] 0.76 -0.98, p = 0.03).

- CV death: 5.3% vs. 5.8%
- MI: 2.8% vs. 2.8%
- Stroke: 2.9% vs. 3.0%
- Hospitalization for HF: 3.2% vs. 4.4% (HR 0.71, 95% CI 0.56-0.90)

Secondary outcomes for finerenone vs. placebo:

- Kidney failure (sustained decrease from baseline of ≥40% in GFR, or death from renal cause): 9.5% vs. 10.8% (HR 0.87, 95% CI 0.76-1.01)
- End-stage kidney disease (ESKD): 0.9% vs. 1.3% (HR 0.64, 95% CI 0.41-0.995)
- All-cause hospitalizations: 42.7% vs. 43.8%
- All-cause mortality: 9% vs. 10.1% (HR 0.89, 95% CI 0.77-1.04)
- Hyperkalemia: 10.8% vs. 5.3%

FIDELITY pooled analysis (n = 13,171): Included patients from FIDELIO-DKD and FIGARO-DKD.

- CV death, MI, stroke, hospitalization for HF, for finerenone vs. placebo: 12.7% vs. 14.4% (HR 0.86, 95% CI 0.78-0.95, p = 0.0018)
- Time to kidney failure, sustained ≥57% decrease in eGFR from baseline, or renal death, for finerenone vs. placebo: 5.5% vs. 7.1% (HR 0.77, 95% CI 0.67-0.88, p = 0.0002)

Interpretation:

The results of this trial indicate that finerenone has salutary effects on CV outcomes among patients with T2DM and CKD, who were on a background of maximal RAS blockade therapy, primarily due to a reduction in hospitalization for HF. There was also a reduction in ESKD. There was a higher risk of hyperkalemia with finerenone. These results extend findings from FIDELIO-DKD and included patients with less severe CKD, including CKD stages 1 and 2 with severe albuminuria. The pooled FIDELITY analysis confirms a benefit in CV and renal outcomes with finerenone. Of note, patients with symptomatic HFrEF were excluded from both trials.

Finerenone is a novel, nonsteroidal, selective mineralocorticoid receptor antagonist (MRA) with anti-inflammatory and antifibrotic effects. It is felt to have higher potency and less hyperkalemia than steroidal MRAs such as spironolactone and eplerenone. Similar efficacy has been reported with SGLT2 inhibitors such as dapagliflozin, empagliflozin, canagliflozin, and sotagliflozin among patients with T2DM and CKD. It is unclear whether both therapies could be used together (only ~8% of patients in this trial were on SGLT2 inhibitors at baseline), or if one would be considered first-line compared with the other.

TOMAHAWK: Immediate Coronary Angiography vs. Delayed Angiography in OHCA Patients Without ST-Segment Elevation

Aug 29, 2021

ACC News Story

Performing immediate coronary angiography in patients with resuscitated out-of-hospital cardiac arrest (OHCA) without ST-segment elevation provided no benefit over a delayed/selective approach with respect to 30-day risk of death from any cause, according to findings from the TOMAHAWK trial presented at ESC Congress 2021 and published in the *New England Journal of Medicine*.

The multicenter trial randomized 554 patients with successfully resuscitated OHCA and evidence of ST-segment elevation to either immediate coronary angiography or initial intensive care assessment with delayed or selective angiography. The primary end point was death from any cause at 30 days, while secondary end points included a composite of death from any cause or severe neurologic deficit at 30 days.

At 30 days, 143 of 265 patients (54%) in the immediate-angiography group compared with 122 of 265 patients (46%) in the delayed-angiography group had died. The secondary endpoints occurred more frequently in the immediate angiography group (64.3%) than in the delayed-angiography group (55.6%), for a relative risk of 1.16 – a finding that principal investigator **Steffen Desch, MD**, noted is "hypothesis generating." Results from other values, such as length of ICU stay, peak troponin release, myocardial infarction or rehospitalization for congestive heart failure did not differ between groups. Additionally, there were no differences between groups in safety endpoints including moderate or severe bleeding, stroke and acute renal failure requiring renal replacement therapy.

"TOMAHAWK was the second and largest randomized trial addressing the question of early coronary angiography in OHCA patients without ST-segment elevation," said Desch. "Like the COACT trial we found that early angiography was not superior to a delayed/selective approach. COACT was restricted to patients with shockable rhythm and TOMAHAWK extends the findings to patients with non-shockable rhythm." He added that "the results of the trial [also] suggest that patients without a significant coronary lesion as the trigger of cardiac arrest do not benefit from an invasive approach and might even be harmed."