

# COMISSÃO DE DEFESA DOS DIREITOS DA PESSOA IDOSA

**Aspectos terapêuticos em doenças valvares do coração**

**Sessão da Câmara dos Deputados**

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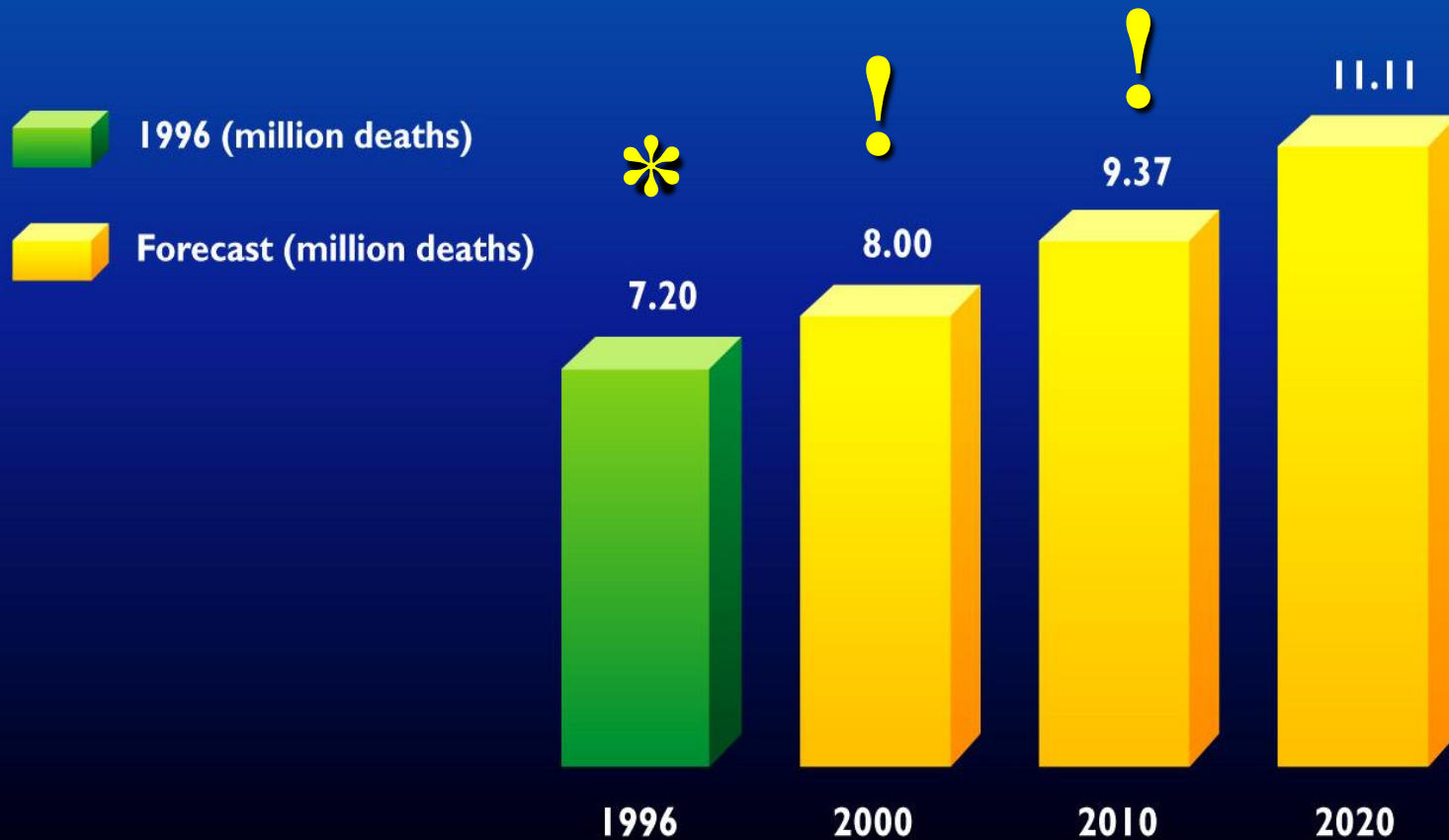
**Sem conflitos de interesse a declarar**

# **Mortalidade mundial/100.000**

## **Global Burden of Disease - 1996**

<b>Coronary disease</b>	<b>7.2</b>
<b>Cancer</b>	<b>6.3</b>
<b>Cerebrovascular disease</b>	<b>4.6</b>
<b>Acute lower respiratory tract infections</b>	<b>3.9</b>
<b>Tuberculosis</b>	<b>3.0</b>
<b>COPD (chronic obstructive pulmonary disease)</b>	<b>2.9</b>
<b>Diarrhea (including dysentery)</b>	<b>2.5</b>
<b>Malaria</b>	<b>2.1</b>
<b>AIDS</b>	<b>1.5</b>
<b>Hepatitis B</b>	<b>1.2</b>

# MORTALIDADE POR DAC



# Estágios de transição epidemiológica

- Desnutrição, infecções, ↑mortalidade infantil, ↓expectativa de vida
- ↑ Saúde pública, controle de infecções, ↑nutrição, ↓ mortalidade infantil, ↑ expectativa de vida
- Emergência de hipertensão arterial e aterosclerose, ↑ ingestão calórica e gordurosa, ↓ atividade física, ↑ mortalidade por doença crônica não transmissível
- DCV e câncer predominantes em morbimortalidade, afetando mais idosos, melhora do tratamento retarda desfechos fatais
- ↑ : Diabetes melito, hipertensão, sobrepeso/obesidade, cessando declínio do tabagismo, inatividade física, estresse emocional.

# Estágios da Transição Epidemiológica e Valvopatias Cardíacas

## Estágios transicionais

## Tipo de doença CV

- Pestilência e desnutrição  
Doença reumatismal, valvopatias, miocardiopatias carenciais
- Pandemias em remissão  
reumatismal, valvopatias, hipertensão, coronariopatia, AVC  
Doença
- Degenerativas e fatores humanos  
Coronariopatia, AVC
- Associadas a longevidade  
Coronariopatia, AVC, Valvopatias, Insuficiência cardíaca
- Inatividade, obesidade  
Coronariopatia, AVC, Insuficiência cardíaca, Valvopatias

# Estágios da transição epidemiológica

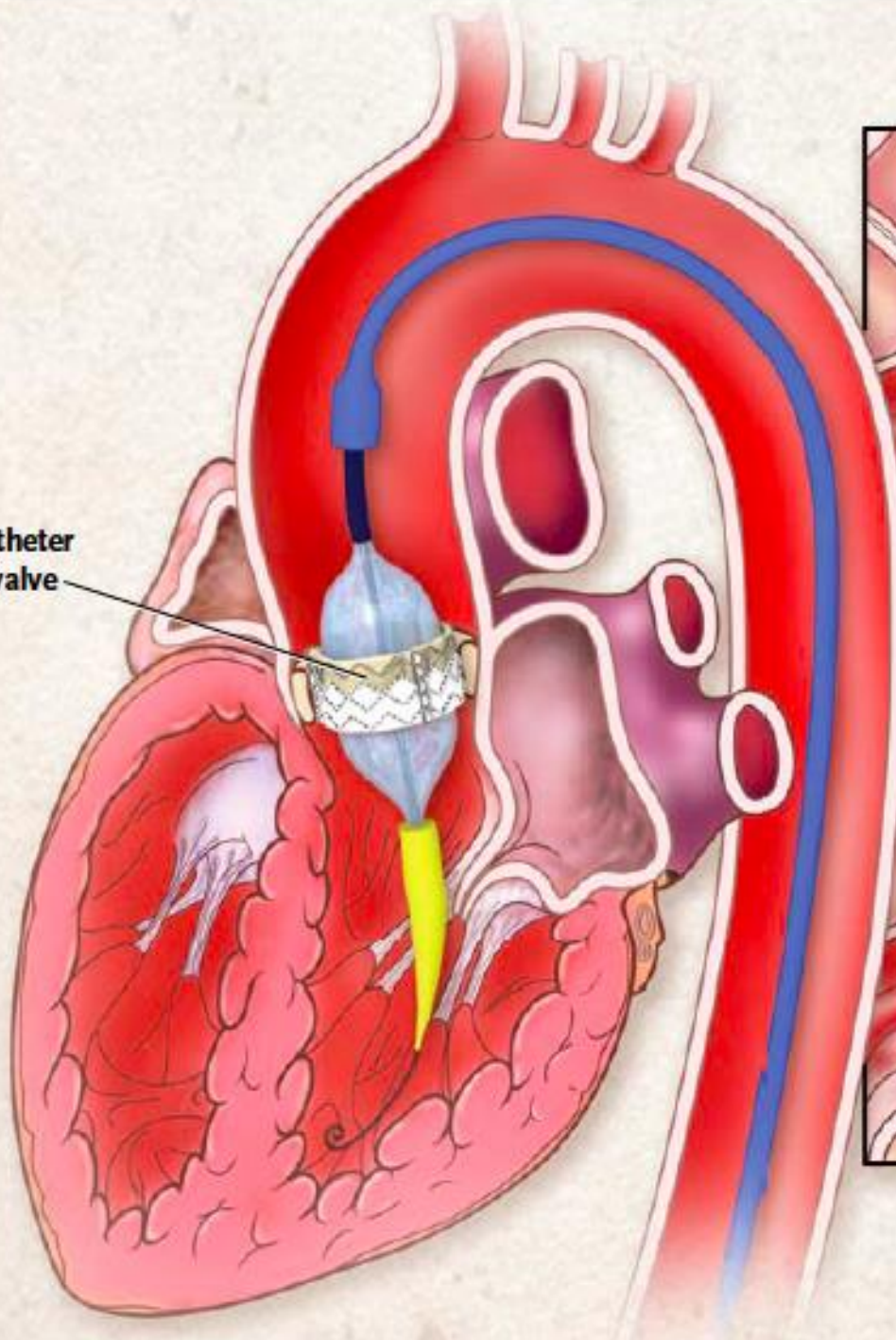
## Mortalidade por doença cardiovascular

Doenças	Mort. CV (%)
• Pestilência e desnutrição	<10
• Pandemias em remissão	10-35
• Degenerativas e fatores humanos	35-65
• Associadas a longevidade	40-50
• Inatividade, obesidade	33

Impacto global da doença cardíaca valvar  
< DAC, AVC, HAS, obesidade, diabetes melito.

- Doença reumatismal (12-65% das hospitalizações cardiovasculares - países em desenvolvimento)
- Valva aórtica bicúspide : 0.5 a 1.5% recém-nascidos.
- Degeneração aórtica com longevidade (53.5 em 1990 para 64.3/100.000 em 2017)\*.
- Endocardite infecciosa : 4-7/100.10<sup>3</sup>/ano

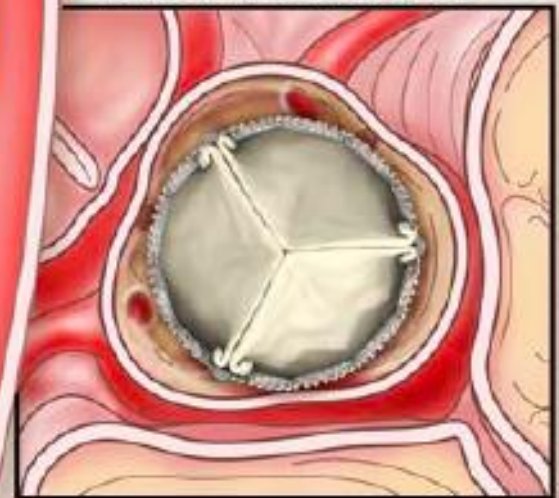
Transcatheter  
aortic valve



Aortic stenosis



Transcatheter aortic valve

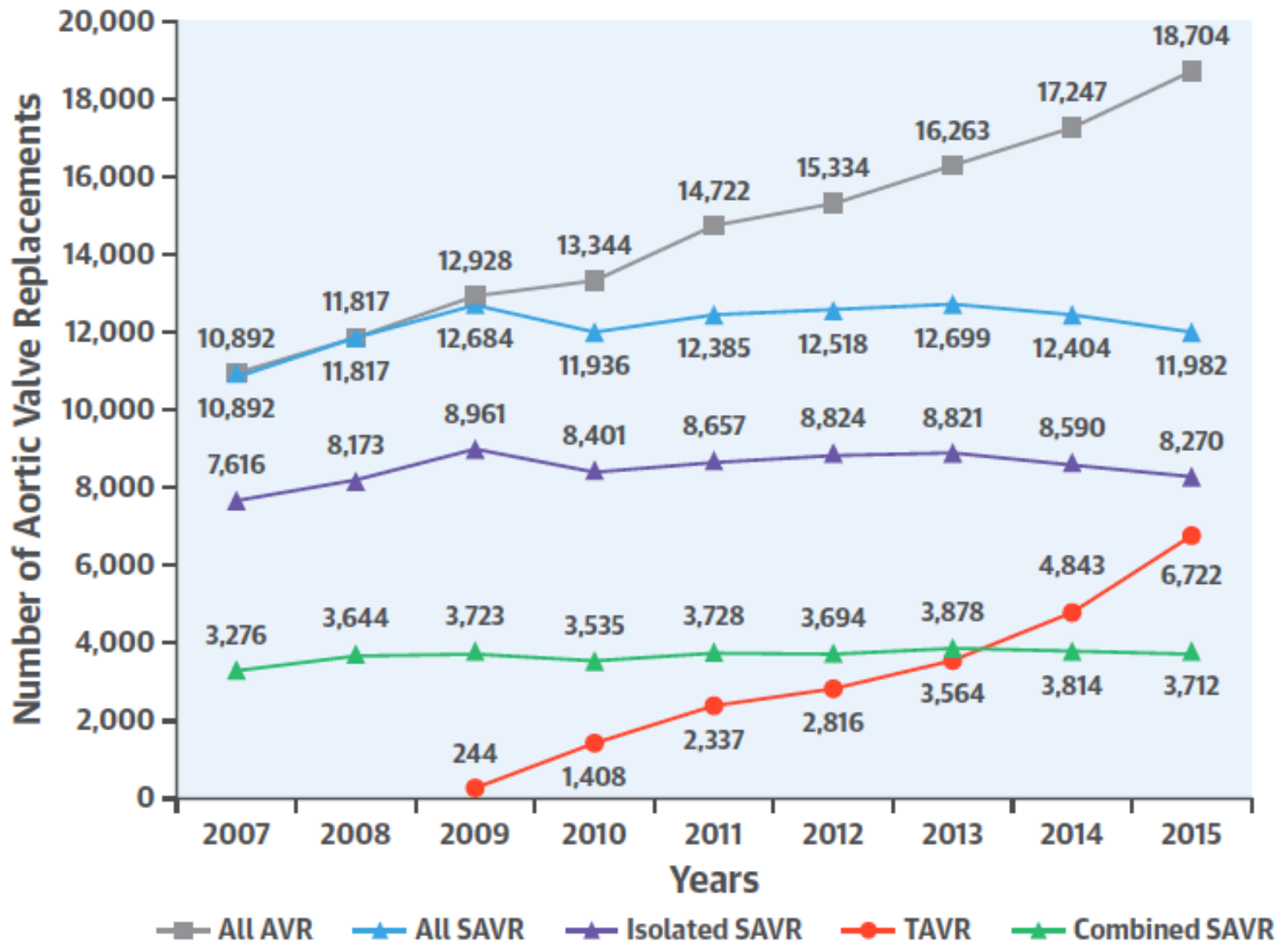




# Tratamento da Estenose Aórtica Valvar

- A mais frequente valvopatia em idosos.
- Cirurgia clássica há 50 anos, de eleição com baixo risco de mortalidade
- Implante de prótese transcaterter  $\cong$  20 anos
- Registro Francês – Resultados em 2015
  - 46% dos implantes por TAVI em idades : 80-84
  - 88% de procedimentos TAVI em idosos  $\geq$  85anos

## A Changes in Number of Aortic Valve Replacements From 2007 to 2015



*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

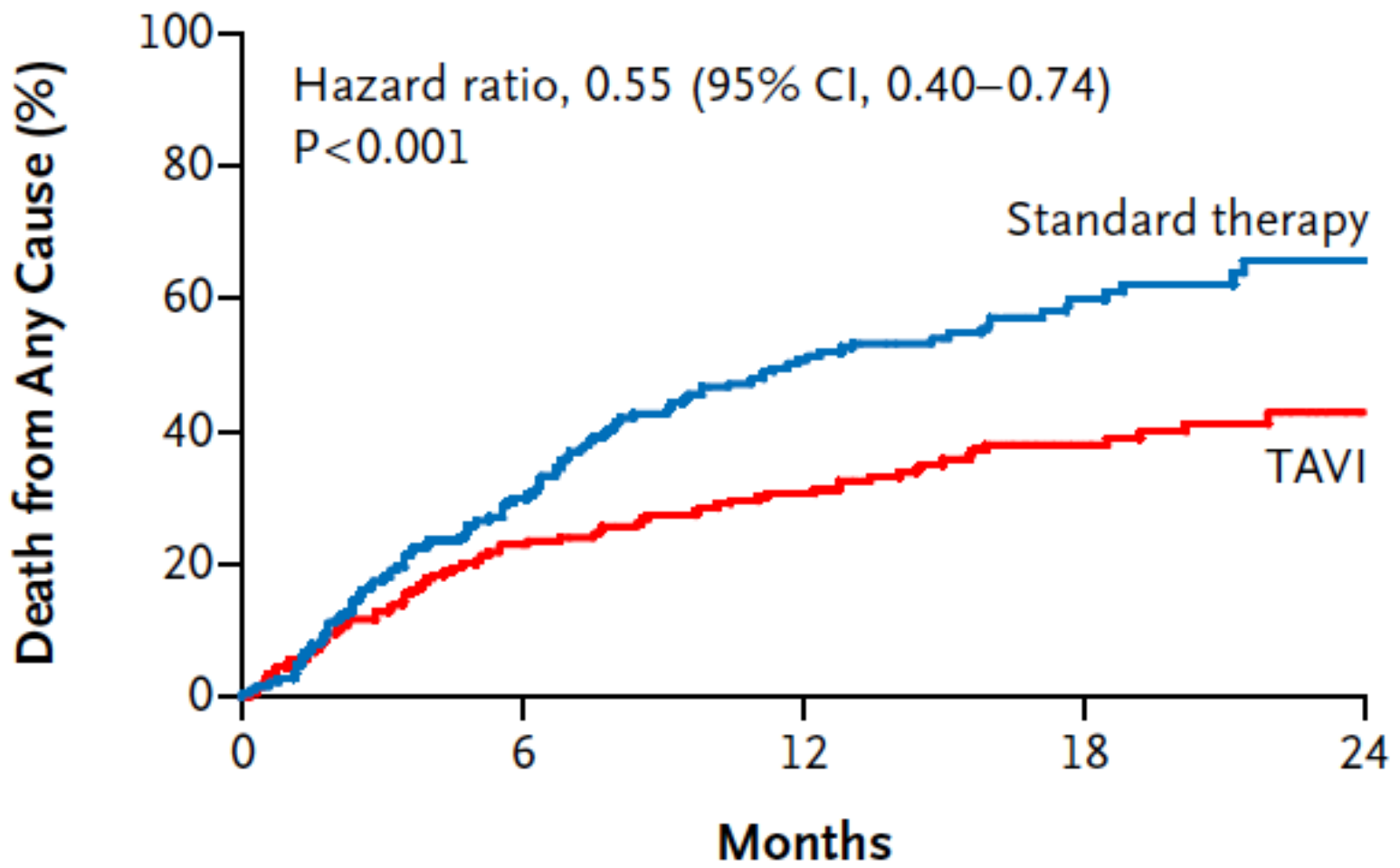
OCTOBER 21, 2010

VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis  
in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,  
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,  
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,  
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D.,  
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,  
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*

A



**No. at Risk**

TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

The use of transcatheter aortic-valve replacement has been shown to reduce mortality among high-risk patients with aortic stenosis who are not candidates for surgical replacement. However, the two procedures have not been compared in a randomized trial involving high-risk patients who are still candidates for surgical replacement.

#### **METHODS**

At 25 centers, we randomly assigned 699 high-risk patients with severe aortic stenosis to undergo either transcatheter aortic-valve replacement with a balloon-expandable bovine pericardial valve (either a transfemoral or a transapical approach) or surgical replacement. The primary end point was death from any cause at 1 year. The primary hypothesis was that transcatheter replacement is not inferior to surgical replacement.

#### **RESULTS**

Leon et al – NEJM 2011; 364: 2187-98

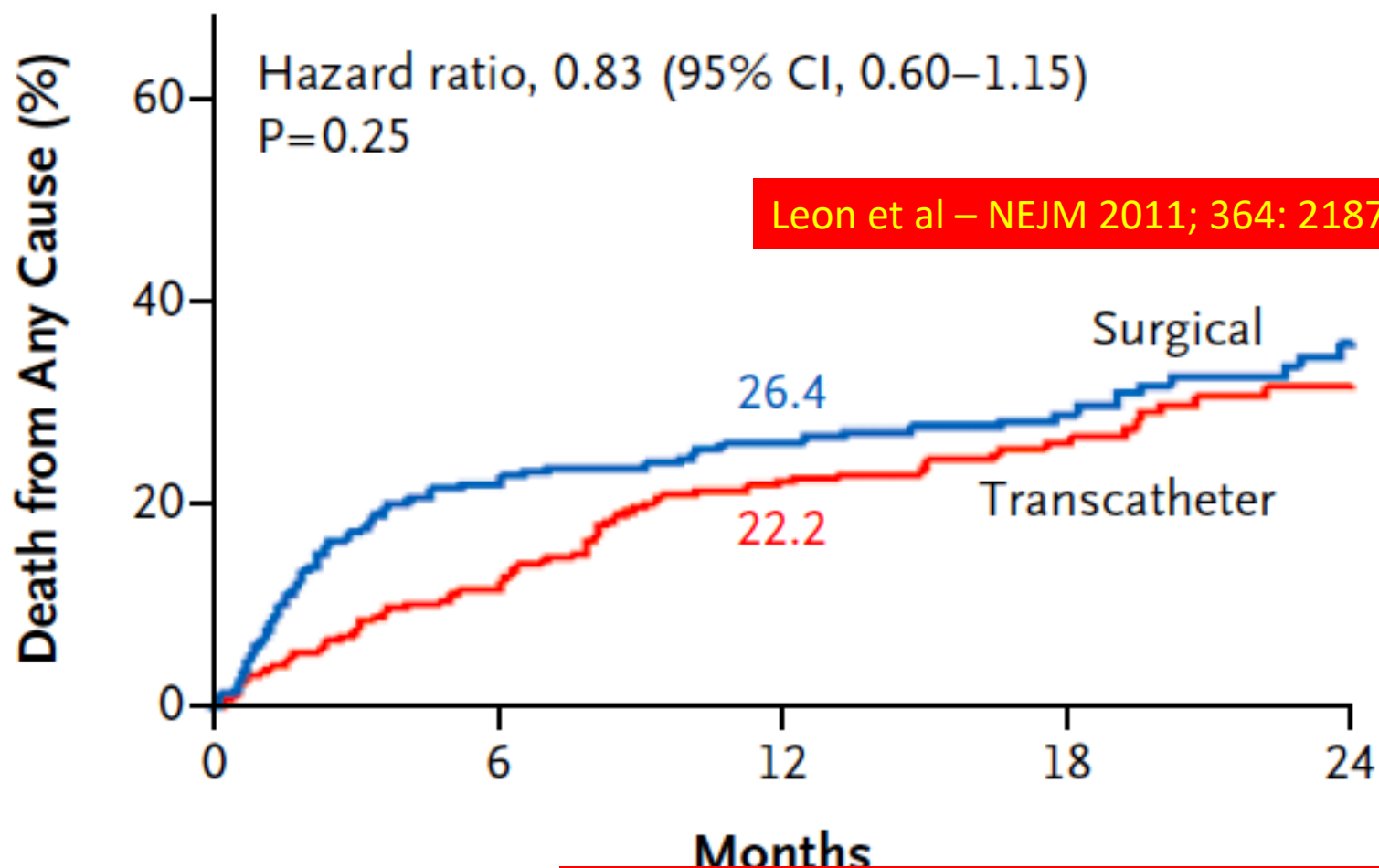
The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days ( $P=0.07$ ) and 24.2% and 26.8%, respectively, at 1 year ( $P=0.44$ ), a reduction of 2.6 percentage points in the transcatheter group (upper limit of the 95% confidence interval, 3.0 percentage points; predefined margin, 7.5 percentage points;  $P=0.001$  for noninferiority). The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days ( $P=0.20$ ) and 5.1% and 2.4%, respectively, at 1 year ( $P=0.07$ ). At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs. 3.2%,  $P<0.001$ ); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%,  $P<0.001$ ) and new-onset atrial fibrillation (8.6% vs. 16.0%,  $P=0.006$ ). More patients undergoing transcatheter replacement had an improvement in symptoms at 30 days, but by 1 year, there was not a significant between-group difference.

Pacientes com estenose valvar aórtica grave, de alto risco de morte se tratados com cirurgia

#### **CONCLUSIONS**

In high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks. (Funded by

## B Death from Any Cause, Transfemoral-Placement Cohort



### No. at Risk

Transcatheter	244	215	188	119	59
Surgical	248	180	168	109	56

Pacientes com estenose valvar aórtica grave, de alto risco de morte se tratados com cirurgia

## BACKGROUND

Previous trials have shown that among high-risk patients with aortic stenosis, survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. We evaluated the two procedures in a randomized trial involving intermediate-risk patients.

## METHODS

We randomly assigned 2032 intermediate-risk patients with severe aortic stenosis, at 57 centers, to undergo either TAVR or surgical replacement. The primary end point was death from any cause or disabling stroke at 2 years. The primary hypothesis was that TAVR would not be inferior to surgical replacement. Before randomization, patients were entered into one of two cohorts on the basis of clinical and imaging findings; 76.3% of the patients were included in the transfemoral-access cohort and 23.7% in the transthoracic-access cohort.

## RESULTS

The rate of death from any cause or disabling stroke was similar in the TAVR group and the surgery group ( $P=0.001$  for noninferiority). At 2 years, the Kaplan–Meier event rates were 19.3% in the TAVR group and 21.1% in the surgery group (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09;  $P=0.25$ ). In the transfemoral-access cohort, TAVR resulted in a lower rate of death or disabling stroke than surgery (hazard ratio, 0.79; 95% CI, 0.62 to 1.00;  $P=0.05$ ), whereas in the transthoracic-access cohort, outcomes were similar in the two groups. TAVR resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation.

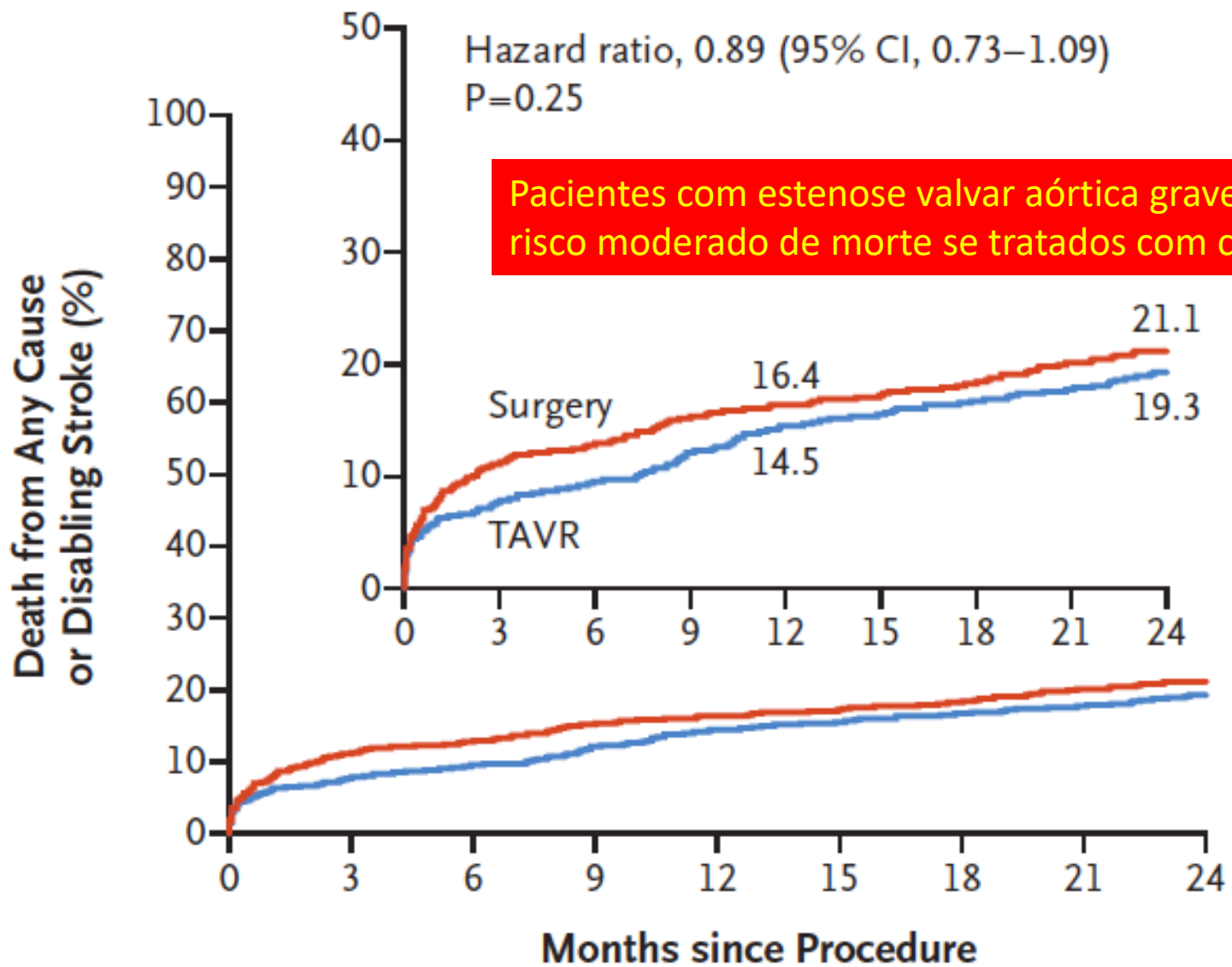
## CONCLUSIONS

In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. (Funded by Edwards Life-

Pacientes com estenose valvar aórtica grave, de risco moderado de morte se tratados com cirurgia

Leon et al NEJM 2016; 374: 1609-20

# A Intention-to-Treat Population



## No. at Risk

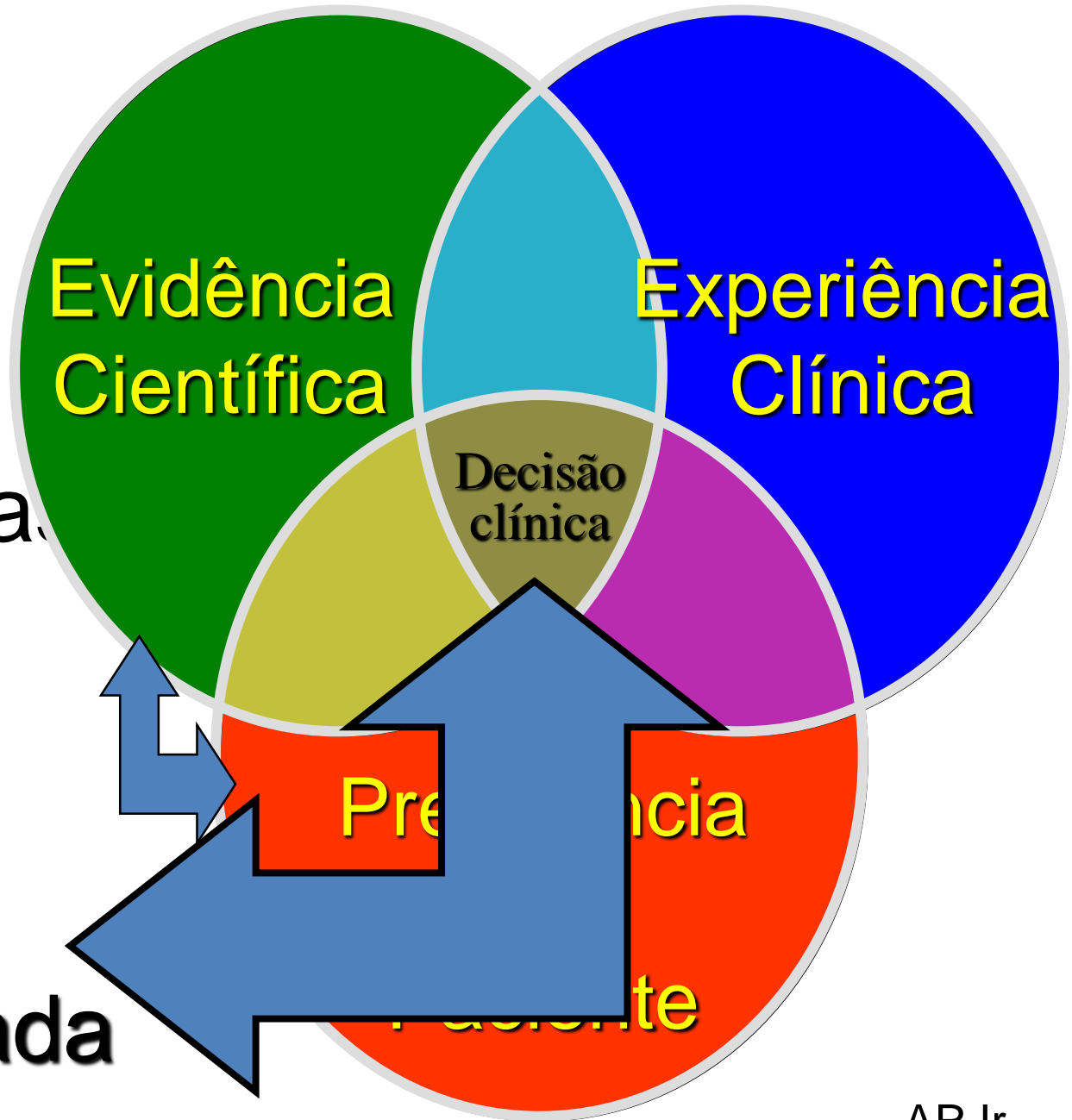
TAVR	1011	918	901	870	842	825	811	801	774
Surgery	1021	838	812	783	770	747	735	717	695

Leon et al NEJM 2016; 374: 1609-20



Medicina  
Embasada  
Em Evidência

Decisão  
Compartilhada



# **NÃO RETORNAM JAMAIS**

- 1. A seta desferida**
- 2. A palavra proferida**
- 3. A oportunidade perdida**

***Provérbio  
árabe***

Latin American and the Caribbean  
28.8%  
(601 million)

Middle East and North Africa  
42.3%  
(422 million)

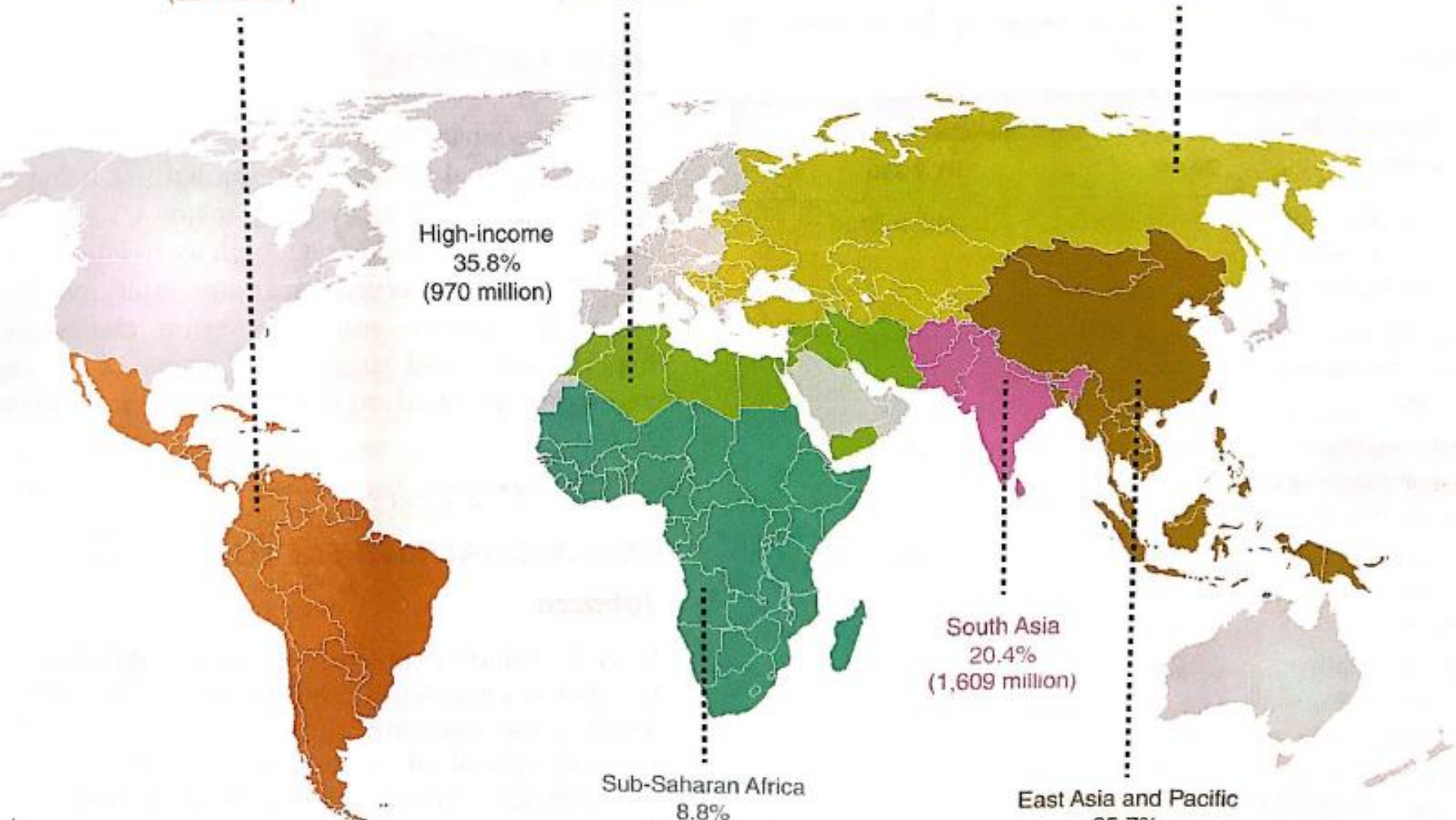
Europe and Central Asia  
58.2%  
(404 million)

High-income  
35.8%  
(970 million)

South Asia  
20.4%  
(1,609 million)

Sub-Saharan Africa  
8.8%  
(823 million)

East Asia and Pacific  
35.7%  
(1,991 million)

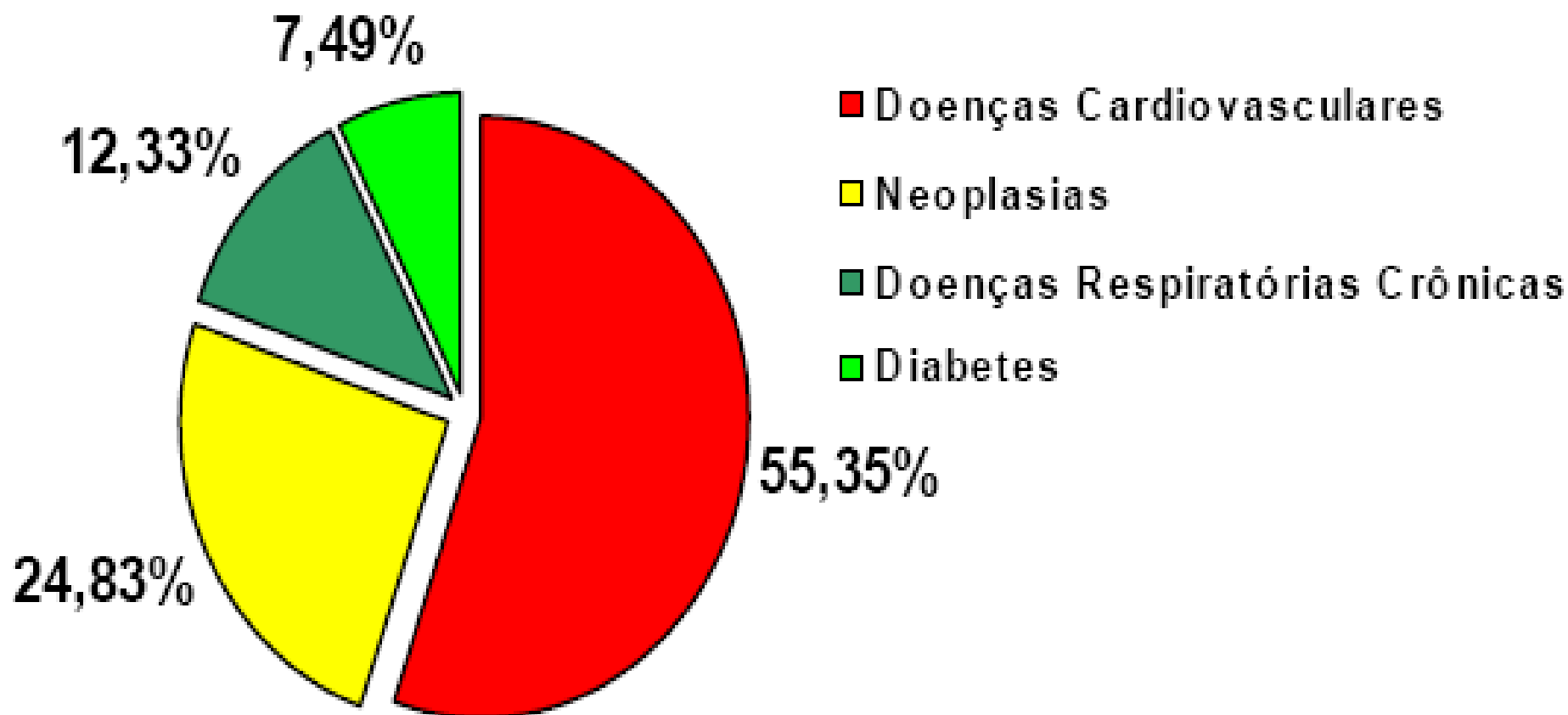


# Doenças Crônicas Não Transmissíveis Brasil - 2002

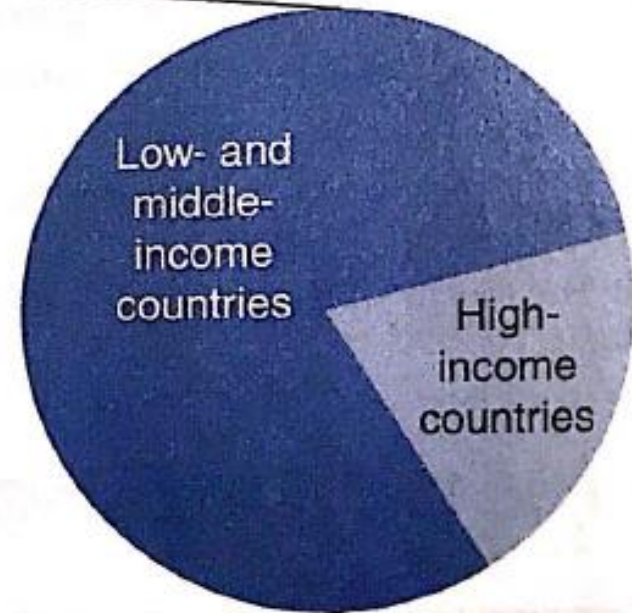
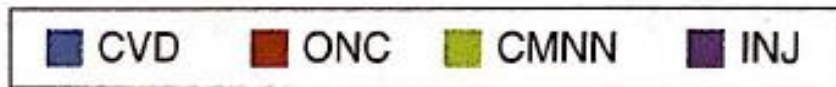
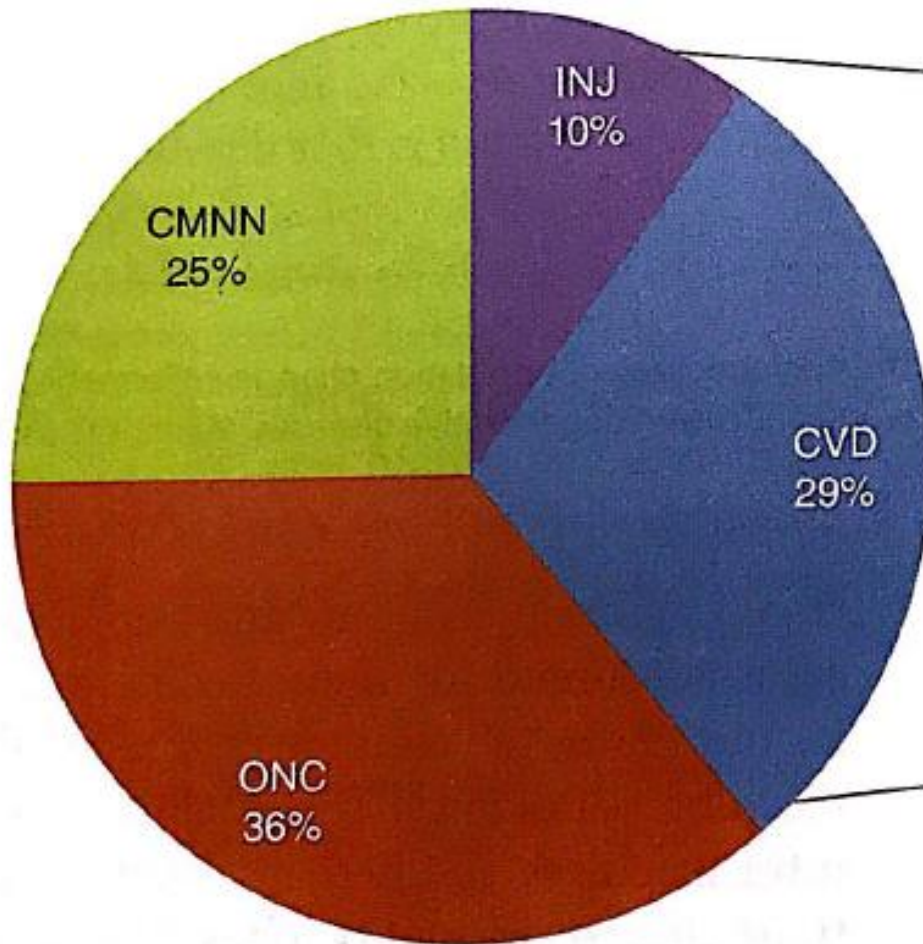
Doenças Crônicas Não Transmissíveis Brasil - 2002

Mortalidade por Grupos de Causas

Sexo Masculino e Feminino - Todas as Idades



Global deaths by cause, 2010



**BACKGROUND** Transcatheter aortic valve replacement (TAVR) has emerged as an alternative to surgical aortic valve replacement (SAVR), but unbiased data regarding evolution of the treatment of patients with aortic stenosis at the nationwide level are scarce.

**OBJECTIVES** This study sought to evaluate the number of aortic valve replacements (AVRs) performed in France, changes over time, and the effect of the adoption of TAVR.

**METHODS** Based on a French administrative hospital-discharge database, the study collected all consecutive AVRs performed in France between 2007 and 2015.

**RESULTS** A total of 131,251 interventions were performed: 109,317 (83%) SAVR and 21,934 (17%) TAVR. AVR linearly increased (from 10,892 to 18,704;  $p$  for trend  $<0.0001$ ) mainly due to a marked increase in TAVR (from 244 to 6,722;  $p$  for trend = 0.0004), whereas SAVR remained stable (from 10,892 to 11,982;  $p$  for trend = 0.18). Parallel to a decrease in the Charlson index ( $p$  for trend  $<0.05$ ), SAVR and TAVR in-hospital mortality rates significantly declined (both  $p$  for trend  $<0.01$ ). The number of TAVRs significantly increased in all age categories ( $<75$ , 75 to 79, 80 to 84, and  $\geq 85$  years of age; all  $p$  for trend = 0.003), but reached or even exceeded SAVR in the 2 oldest categories. Although mortality rates declined for both isolated SAVR and TAVR, it became similar or slightly lower for TAVR than for isolated SAVR in 2015 in the 3 oldest age categories even if it did not reach statistical significance ( $p = 0.66$ ,  $p = 0.47$ , and  $p = 0.06$ , respectively).

**CONCLUSIONS** The number of AVRs markedly increased in France between 2007 and 2015 due to the wide adoption of TAVR, which represented one-third of all AVRs in 2015. Patients' profile improved, suggesting that patients are referred earlier, and in-hospital mortality declined in all AVR subsets. Despite a worse clinical profile, the immediate outcome of TAVR compared favorably to isolated SAVR in patients  $>75$  years of age. The results may have major implications for clinical practice and policymakers. (J Am Coll Cardiol 2018;71:1614-27) © 2018 by the American College of Cardiology Foundation.