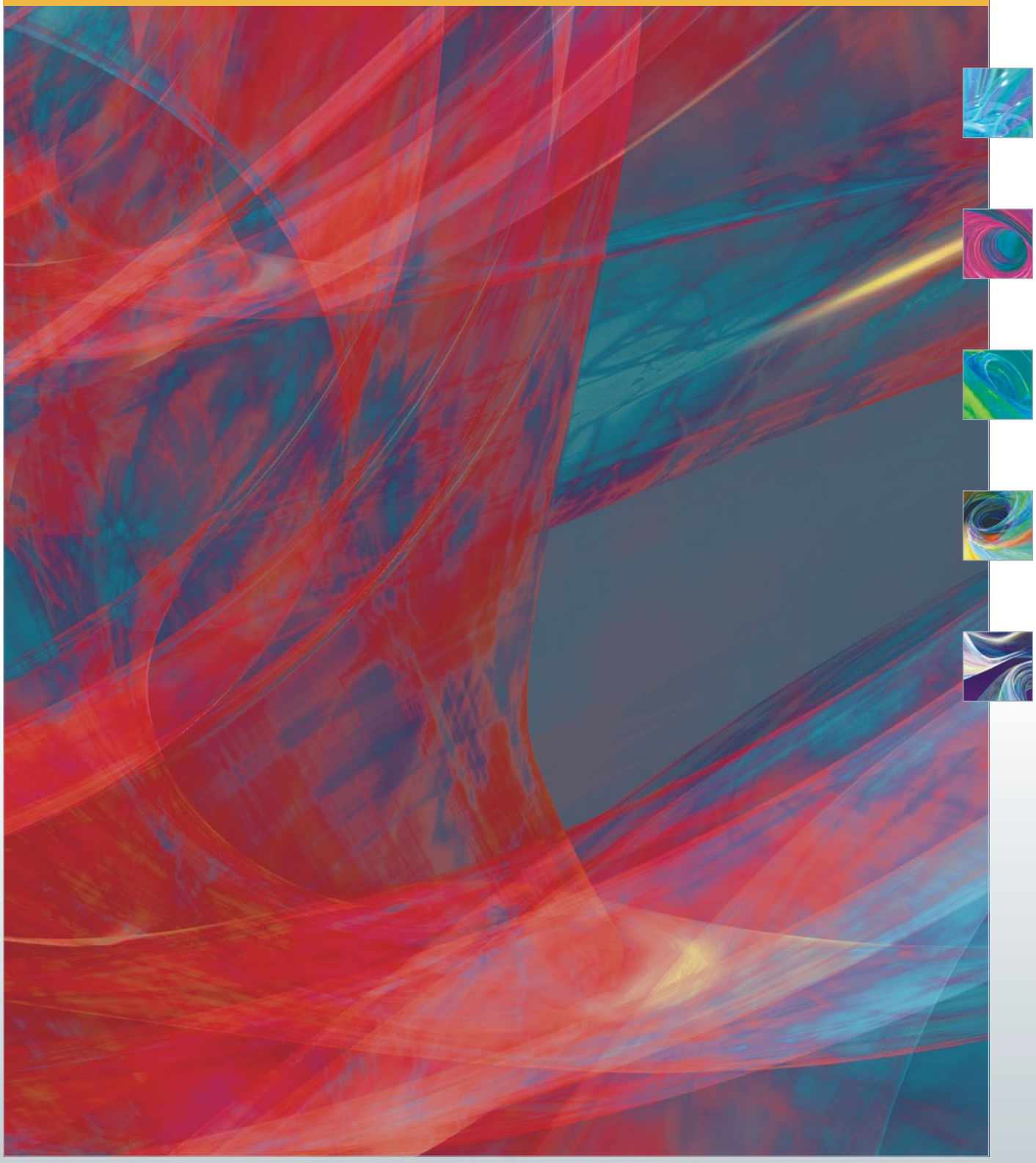
Alliance FOR AGING RESEARCH

Chronic Disease and Medical Innovation in an Aging Nation

The Silver Book®: Valve Disease

FOCUS ON AORTIC STENOSIS



The Silver Book®: Valve Disease

FOCUS ON AORTIC STENOSIS

Aortic stenosis is one of the most common and serious types of heart valve disease. Aortic stenosis can be debilitating, costly, and deadly. Survival rates without treatment for severe symptomatic aortic stenosis are low at 50% at 2 years after symptom onset, and 20% at 5 years. Fortunately, innovative treatments are saving lives and aortic stenosis can be successfully treated with valve replacement in patients of all ages.

■ **Facts in silver type deal specifically with older Americans.**

Cost of Aortic Stenosis

Prevalence & Incidence

- In 2016, as many as 5.8 million U.S. adults had aortic valve disease (AVD).

  Alliance for Aging Research generated statistic, based on 2005 percentage prevalence estimates by Bach et al. 2007, *Prevalence, Referral Patterns, Testing, & Surgery in AVD* AND U.S. Census 2016, *American Fact Finder*

- Aortic stenosis (AS) is among the most common forms of heart valve disease (HVD), affecting 2% to 3% of the adult U.S. population.

  Clark et al. 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed Severe Aortic Stenosis*

- Prevalence estimates for AS are likely low. A U.K. population screening found previously undetected HVD in 1 in 2 adults ages 65+.

  D'Arcy et al. 2016, *Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People*

Age — A Major Risk Factor

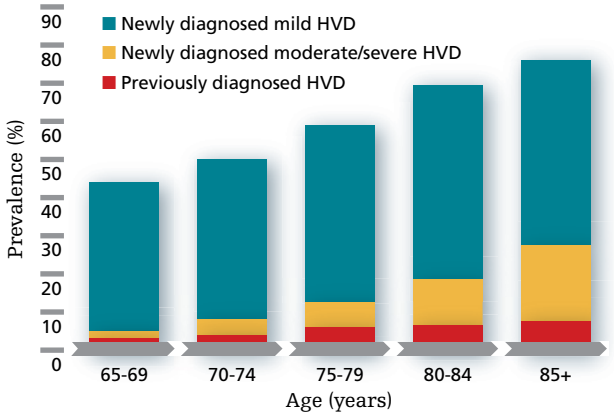
- In 2016, an estimated 5.2 million U.S. adults ages 65+ had AVD.

  Alliance for Aging Research generated statistic, based on 2005 percentage prevalence estimates by Bach et al. 2007, *Prevalence, Referral Patterns, Testing, & Surgery in AVD* AND U.S. Census 2016, *American Fact Finder*

- An estimated 12.4%, or ~2.5 million people ages 75+ in North America, have AS.

  Osnabrugge et al. 2013, *Aortic Stenosis in the Elderly*

- Population Prevalence of Heart Valve Disease in U.K. According to Age



D'Arcy et al. 2016, *Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People*

Cost of Aortic Stenosis continued >

The Burden of Aortic Stenosis

Human Burden

- Patients with severe symptomatic aortic stenosis (sSAS) who do not undergo valve replacement have survival rates as low as 50% at two years and 20% at 5 years after the onset of symptoms.

  Otto 2000, *Timing of Aortic Valve Surgery*

- Medicare patients with sSAS who do not undergo treatment have an average lifespan of 1.8 years.

  Clark et al. 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed SAS*

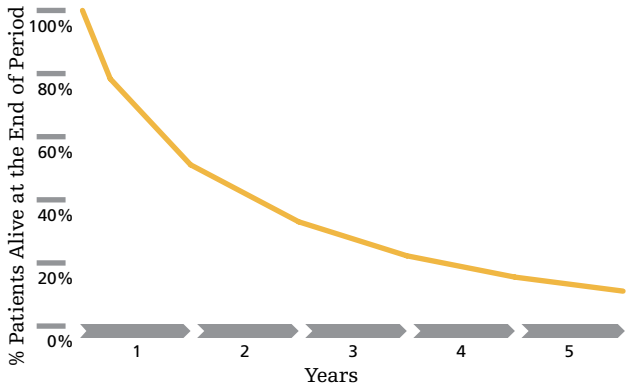
- Waiting for treatment for sSAS can be deadly, with 1-month mortality at 3.7% and 6-month mortality at 11.6% (measured from the time intervention was recommended).

  Malaisrie et al. 2014, *Mortality While Waiting for AVR*

- In 2014, all-cause mortality for aortic valve disorders was 34,408 in the U.S.

  Benjamin et al. 2017, *Heart Disease & Stroke Statistics — 2017 Update*

- Survival Rates Over 5 Years for Patients with Medically Managed Severe Aortic Stenosis



Clark et al. 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed SAS*

- Medicare sSAS patients who do not undergo treatment have an average of 1.9 hospital admissions per year and prolonged lengths of stay — 11.5 hospital days per patient-year.

  Clark et al. 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed SAS*

Economic Burden

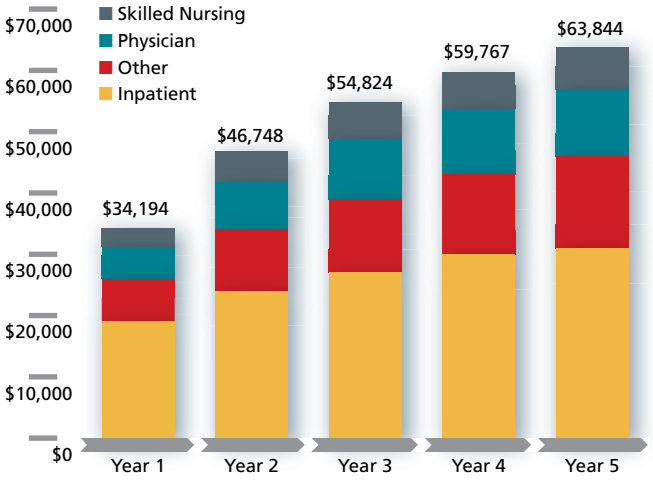
- AVD (symptomatic and asymptomatic) costs the U.S. $10.2 billion in direct costs each year.

  Moore et al. 2016, *The Direct Health-Care Burden of Valvular Heart Disease*

- Symptomatic aortic stenosis (SAS) patients who do not undergo treatment cost Medicare as much as $1.3 billion each year due to rehospitalization, prolonged stays, admissions to skilled nursing facilities, and use of hospice care.

  Clark et al 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed SAS*

- Mean 5-Year Cumulative Total Medical Costs Per Medically Managed (No AVR) Severe AS Patient



Clark et al. 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed Severe Aortic Stenosis*

Cost of Aortic Stenosis continued >

Cost of Aortic Stenosis continued

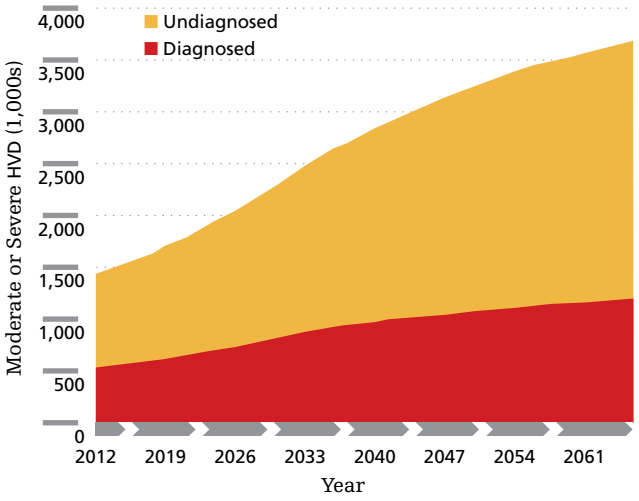
- Five-Year Health Care Resource Use in Medically Managed SAS Patients

Resource	Resource Use
Acute inpatient hospitalization	100%
Hospitalizations	4.4 (mean)
Hospital days	26.7 (mean)
Long-term care hospital	3.4%
Inpatient rehab facility	9.5%
Skilled nursing facility	52%
Skilled nursing days	25.5 (mean)
Hospice care	27.6%
Home health care	57.4%
Outpatient hospital care	84.2%
Physician services	100%
Durable medical equipment use	70.9%
Dialysis services	5.7%

Clark et al. 2012, *Five-Year Clinical and Economic Outcomes Among Patients with Medically Managed SAS*

The Future Cost

- Projections of Significant Heart Valve Disease — Diagnosed & Undiagnosed — in the 65+ U.K. Population



D'Arcy et al. 2016, *Large-Scale Community Echocardiographic Screening Reveals a Major Burden of Undiagnosed Valvular Heart Disease in Older People*

Awareness of HVD

Not all AS patients experience symptoms but they can include chest pain, fatigue, difficulty walking short distances or up stairs, shortness of breath, lightheadedness, dizziness, or fainting. Those that experience symptoms may miss them or dismiss them as "normal" signs of aging. With proper detection and treatment, AS patients can be successfully treated — making awareness critical.

- A survey of Americans found that only 1 in 4 know "somewhat" or a "great deal" about HVD. Forty percent know nothing about the disease.

  BRS 2016, *Report of Findings from National Survey Research on Public Awareness of HVD*

- Of those Americans surveyed ages 65+, 30% know nothing about HVD.

  BRS 2016, *Report of Findings from National Survey Research on Public Awareness of HVD*

- More than 2/3 of valve disease patients knew a limited amount or nothing about HVD before their diagnosis.

  BRS 2016, *Report of Findings from Opinion Research Among Heart Valve Disease Patients*

- Six in 10 patients did not have or recognize symptoms of HVD and were only diagnosed after going to their doctor for a regular check-up or a visit for something else.

  BRS 2016, *Report of Findings from Opinion Research Among Heart Valve Disease Patients*

- More than 40% of heart murmurs — detected with a stethoscope and sometimes the first sign of HVD — are missed by family practitioners.

  Vukanovic-Criley et al. 2006, *Competency in Cardiac Examination Skills in Medical Students, Trainees, Physicians, and Faculty*

- AS is often undertreated — one study found that 56% of sSAS patients referred to a cardiothoracic surgeon were not operated on.

  Bach 2011, *Prevalence & Characteristics of Unoperated Patients with Severe AS*

Innovative Medical Research

The Human Value

- In 2010, ~67,500 surgical aortic valve replacements (SAVR) were performed in the U.S.

  Clark et al. 2012, *Clinical and Economic Outcomes After SAVR in Medicare Patients*

- Patients with SAS ages 80+ who underwent SAVR have 1-year, 2-year, and 5-year survival rates of 87%, 78%, and 68% respectively — compared with 52%, 40%, and 22% for those patients who did not have surgery.

  Varadarajan et al. 2006, *Survival in Elderly Patients with SAS is Dramatically Improved by AVR*

- At 1-year, SAS patients with intermediate surgical mortality risk who underwent transcatheter aortic valve replacement (TAVR), had all-cause mortality rates of 7.4% (compared to 13% for SAVR), disabling stroke rates of 2.3% (compared to 5.9% for SAVR), and rehospitalization rates of 11.4% (compared to 15.1% for SAVR).

  Thourani et al. 2016, *TAVR versus SAVR in Intermediate-Risk Patients*

- From approval in 2011 through 2015, >54,000 TAVRs were preformed in 418 centers in 48 states.

  Grover et al. 2017, *2016 Annual Report of The STS/ACC Transcatheter Valve Therapy Registry*

- A study of sSAS patients who received TAVR found 30-day mortality of 2.2% for those who were high risk of surgical mortality/inoperable, and 1.1% for those at intermediate surgical mortality risk.

  Kodali et al. 2016, *Early Clinical and Echocardiographic Outcomes after SAPIEN 3 TAVR in Inoperable, High-Risk and Intermediate-Risk Patients with AS*

- SAS patients who underwent TAVR experienced quality of life (QoL) improvements from 5.3 at baseline (10 point scale with 10=best imaginable health state) to 6.7 at one year, and 7.4 at four years post-procedure.

  Kovac 2016, *Four-Year Experience with the CoreValve Transcatheter Heart Valve*

- Among treated HVD disease, 96% express "full satisfaction" and 78% are "very satisfied" with their treatment.

  BRS 2016, *Report of Findings from Opinion Research Among HVD Patients*

- TAVR and SAVR in intermediate-risk SAS patients were associated with significant improvements in disease specific status (16 to 22 point improvement on a 100 point scale) and in generic health status (3.9 to 5.1 point improvement on a 36 point scale).

  Baron et al. 2017, *Health Status Benefits of Transcatheter vs Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk*

The Economic Value

- A study of 4,617 patients who underwent aortic valve replacement (AVR) over a period of 20 years found significant gains in life expectancy and quality of life — 43,166 net life-years gained at a net value of $11.2 billion (~$14.2 billion in 2017 dollars).

  Wu et al. 2007, *The Value of Aortic Valve Replacement in Elderly Patients* AND *Bureau of Labor Statistics, CPI Inflation Calculator*

- The cost-effectiveness ratio for SAVR, compared to no surgery, was estimated at $13,528 per quality-adjusted life year (QALY) (~$17,226 in 2017 dollars).

  Wu et al. 2007, *Cost-Effectiveness of AVR in the Elderly* AND *Bureau of Labor Statistics, CPI Inflation Calculator*

- Patients with sSAS considered to be at high surgical risk who underwent TAVR experienced lifetime incremental cost-effectiveness ratios of $55,090 per QALY gained and $43,114 per life-year (LY) gained.

  Reynolds 2016, ***Cost-Effectiveness of TAVR with a Self-Expanding Prosthesis Versus SAVR***

The Silver Book®: Chronic Disease and Medical Innovation in an Aging Nation is an almanac of statistics on the burden of chronic disease and the value of innovation in reducing the human and economic costs of disease. Launched in 2006, *The Silver Book* has become a trusted resource for health policy experts and thought leaders across the nation, and has featured volumes and factsheets on osteoporosis, thrombosis, atrial fibrillation, heart disease, persistent pain, cancer, healthcare-associated infections, infectious diseases & prevention through vaccination, vision loss, diabetes, diabetic retinopathy, and neurological diseases. All data is available on-line where users can access more than 2,900 facts, statistics, graphs, and data from more than 800 agencies, organizations, and experts.

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The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application in order to vastly improve the universal human experience of aging and health.