Evaluation of Patients With Severe Symptomatic Aortic Stenosis Who Do Not Undergo Aortic Valve Replacement

The Potential Role of Subjectively Overestimated Operative Risk

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Background—Some patients with severe symptomatic aortic stenosis (AS) do not undergo aortic valve replacement (AVR) despite demonstrated symptomatic and survival advantages and despite unequivocal guideline recommendations for surgical evaluation.

Methods and Results—In 3 large tertiary care institutions (university, Veterans Affairs, and private practice) in Washtenaw County, Mich, patients were identified with unrefuted echocardiography/Doppler evidence of severe AS during calendar year 2005. Medical records were retrospectively reviewed for symptoms, referral for AVR, calculated operative risk for AVR, and rationale as to why patients did not undergo valve replacement. Of 369 patients with severe AS, 191 (52%) did not undergo AVR. Of these, 126 (66%, 34% of total) had symptoms consistent with AS. The most common reasons cited for absent intervention were comorbidities with high operative risk (61 patients [48%]), patent refusal (24 patients [19%]), and symptoms unrelated to AS (24 patients [19%]). Operated patients had a lower Society of Thoracic Surgery–calculated perioperative mortality risk than unoperated patients (1.8% [interquartile range, 1.0 to 3.0%] versus 2.7% [interquartile range, 1.6 to 5.5%], P<0.001). However, 28 (24%) of 126 unoperated symptomatic patients had a calculated perioperative risk less than the median risk for patients who underwent AVR. Only 57 (30%) of 191 unoperated patients were evaluated by a cardiac surgeon. There were similar rates of intervention across practice settings, and similar rates of unoperated patients despite symptoms and low operative risk.

Conclusions—One third of patients with severe AS are symptomatic but do not undergo AVR, with similar findings in multiple practice environments. For most unoperated patients, objectively calculated operative risks did not appear prohibitive. Despite this, a minority of unoperated patients were referred for surgical consultation. Some patients with severe symptomatic AS may be inappropriately denied access to potentially life-saving therapy. (Circ Cardiovasc Qual Outcomes. 2009;2:533-539.)

Key Words: aortic valve stenosis ■ heart valves ■ standards

Aortic stenosis (AS) is a common condition of the elderly, with a prevalence of 1.2% to 1.8% among patients 65 to 74 years of age, and 4.1% to 5.2% in people ≥75 years of age. The natural history of AS is well established from historical data: after the onset of symptoms of angina pectoris, dyspnea, or syncope, annual mortality approaches 25% and average survival is only 2 to 3 years. Aortic valve replacement (AVR) is the only currently accepted treatment for symptomatic patients with severe AS. In addition, recent and current guidelines support consideration for intervention in some but not all asymptomatic patients, with consideration for exercise stress testing to help stratify risk.

Despite clearly poor outcomes among unoperated patients with symptomatic severe AS, and despite documented symptomatic and mortality benefit associated with AVR, previously published studies suggest that not all patients with indications for intervention undergo surgery. One study in the Netherlands suggested that no intervention was performed in 41% of elderly patients with severe AS and practice guideline indications for intervention. The Euro Heart Survey, conducted during 4 months during 2001 in 25 European countries, suggested that no intervention was performed in 31.8% of patients despite the presence of both severe single-valve disease and severe symptoms. Although symptomatic status was not documented, a survey performed between 1993 and 2003 in Loma Linda, Calif, suggested that 453 (60.9%) of 744 patients with severe AS did not undergo intervention. However, it is not currently known to what degree practice setting influences decisions to operate. Further, although

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Advanced age has been implicated as a mitigating factor against intervention,6–11 other factors affecting decisions for and against intervention have not been previously investigated. The purpose of the present study was to determine in multiple clinical settings the frequency and contributing factors affecting decisions by which patients with severe symptomatic AS do not undergo AVR.

WHAT IS KNOWN

• Aortic valve replacement is associated with both symptomatic improvement and survival advantage among patients with severe symptomatic aortic stenosis. Despite unequivocal guideline recommendations, some patients with severe symptomatic aortic stenosis do not undergo aortic valve replacement.

WHAT THE STUDY ADDS

• This article evaluates the frequency and rationale by which patients with severe aortic stenosis do not undergo aortic valve replacement. In this multicenter study, one third of patients with severe aortic stenosis were found to have symptoms but did not undergo valve replacement. Although high operative risks commonly were cited as a reason not to refer, objectively calculated operative risks did not appear to be prohibitive.

Methods

Study Population

Three medical institutions participated in this study, selected based on common geographic location but distinct patient populations: the University of Michigan, a large, university-based academic tertiary referral center; the Ann Arbor Veterans Affairs (VA) Hospital, a large secondary and tertiary care facility with a cardiac surgery program serving veterans in Michigan and northwestern Ohio; and Michigan Heart and Vascular Institute, a large single-specialty private practice cardiovascular medical group serving southeastern Michigan in affiliation with primary, secondary, and tertiary hospitals.

At each of the participating sites, data from echocardiography examinations performed during calendar year 2005 were interrogated for a finding of severe AS, defined as mean transaortic gradient ≥40 mm Hg, calculated aortic valve area ≤0.9 cm², or overall clinical impression consistent with severe AS. The institutional review boards of each of the respective institutions reviewed and approved the study protocol.

Clinical Data

For patients identified as having an echocardiogram revealing severe AS, electronic medical records were reviewed, and included all inpatient notes, outpatient notes, and results of diagnostic testing at all sites. Primary review at each site was performed by one of the authors (D.S.B. at the University of Michigan, S.K.G. at the VA Hospital, D.S. at Michigan Heart and Vascular Institute). After collation, data were reviewed by that individual and D.S.B.; categorization was established by consensus. Clinical variables were recorded, including patient age and sex, comorbid diseases (including diabetes, hypertension, peripheral vascular disease, chronic lung disease, renal insufficiency, heart failure, pulmonary arterial hypertension, active malignancy, stroke, or dementia), and pertinent current and past medical and surgical history. Any subsequent cardiac testing was investigated, including additional transthoracic or transesophageal echocardiograms, and data from left and right heart catheterization. Special attention was paid to documentation of symptoms potentially referable to AS, including angina pectoris or other chest pain, presyncope or syncope, and dyspnea or other evidence of heart failure. Evaluation by a cardiologist or cardiothoracic surgeon was recorded, as was performance of AVR. For patients who did not undergo surgery, available rationale was recorded. Patients were excluded from analysis if subsequent testing refuted the echocardiographic finding of severe AS, or if insufficient medical data were available after the echocardiogram.

Operative Risk

For all patients with severe AS, whether or not AVR was performed, the anticipated perioperative risk of mortality and perioperative combined morbidity and mortality associated with surgical valve replacement were calculated using the Society of Thoracic Surgery (STS) Adult Cardiac Surgery Risk Calculator12 using historical and clinical data available at the time of the initial echocardiogram documenting severe AS.

Statistical Analysis

Data for categorical variables are reported as number and percent; comparisons between groups were made using x² tests or Fisher exact tests (when the expected value in any of the cells was <5). Continuous variables are reported as mean±SD for variables with normal distribution (age, ejection fraction), or as median and interquartile range (IQR) for variables with nonnormal distribution (perioperative risks). Comparisons between groups of continuous variables with normal distribution were made using unpaired Student t tests (2-tailed). Comparisons between groups of continuous variables with nonnormal distribution were made using Mann–Whitney U tests. Survival was determined using the Kaplan–Meier method; comparison between groups was made using log rank test. For all analyses, symptomatic status was defined at the time of echocardiography; subsequent development of symptoms was not tracked. Patients were considered to be unoperated if no AVR was performed within 2 years of echocardiography; for Kaplan–Meier survival analysis, patients were censored at the time of AVR occurring >2 years after echocardiography. Statistical significance was defined as a P value <0.05. Statistical analysis was performed using SPSS Statistics for Macintosh, version 17.0 (SPSS, Inc).

Results

Study Population

From January 1 to December 31, 2005, 413 patients underwent echocardiographic imaging interpreted to be consistent
with severe AS, including 159 patients at the university medical center, 72 patients at the VA, and 182 at the private medical group. Of these, 44 patients were excluded because of inadequate available medical records after the echocardiogram (n = 1). Of the remaining 369 patients, 178 underwent AVR (80 at the university, 24 at the VA, and 74 at the private group), and 191 were unoperated (75 at the university, 38 at the VA, and 78 at the private group).

Characteristics of the 191 unoperated patients are shown in Table 1. In general, patients were relatively similar between sites. However, all patients in the VA system were men, and patients in the private group were older than patients seen in the other settings.

### Symptoms Associated With AS

Of 191 unoperated patients, 126 had symptoms consistent with AS (Table 2). There were no statistically significant differences between sites in the percentage of symptomatic patients, although there was a nonsignificant trend toward more asymptomatic patients at the VA. Among unoperated patients, symptomatic patients on average were older than asymptomatic patients (75.0 ± 12.5 versus 69.6 ± 12.8 years, P = 0.006). However, the average age of unoperated symptomatic and asymptomatic patients was not statistically different at either the university system (68.0 ± 15.5 versus 68.3 ± 14.1 years, P = 0.94) or the VA (74.9 ± 9.5 versus 67.9 ± 15.4 years, P = 0.11); rather, the difference observed in the group as a whole was attributable to a large and significant difference in ages in the private practice setting (80.8 ± 7.0 versus 72.0 ± 9.4, P < 0.001).

### Referral and Testing

Of 191 patients with unoperated severe AS, 182 (95%) were evaluated by a cardiologist, including 69 of 75 (92%) patients in the university system, 35 of 38 (92%) patients at the VA, and 78 of 78 (100%) patients in the private setting (P = 0.01 compared with university and P = 0.03 compared with VA). Of 191 unoperated patients, 57 (30%) were evaluated by a cardiologist; a greater proportion of patients was evaluated by a cardiologist in the university system (32 of 75 [43%]) compared with the private setting (18 of 37 [23%], P = 0.009) or the VA (7 of 38 [18%), P = 0.008). Of 65 unoperated asymptomatic patients, 13 (20%) underwent exercise stress testing. The proportion of asymptomatic patients evaluated with exercise testing was higher in the private setting (11 of 25 [44%]) than at the university (1 of 22 [5%], P = 0.002) or the VA (1 of 18 [6%), P = 0.006).

### Operative Risk

The calculated risks of perioperative mortality for all patients are shown in Table 3, with comparisons of distributions in Figure 1. The calculated risks of perioperative combined mortality and morbidity are shown in Table 4. For the whole group and at each practice setting, predicted perioperative mortality risk was significantly lower for operated than for unoperated patients. Perioperative mortality risk was significantly lower for the whole group among unoperated asymptomatic compared with unoperated symptomatic patients.

The median STS risk of perioperative mortality in the pooled group of 126 symptomatic patients not undergoing AVR was 3.8% (IQR, 2.1 to 7.3%). Among these, 70 (56%) patients had a calculated operative risk ≤5%. The prevalence at each site of unoperated patients based on symptomatic status and operative risk is shown in Figure 2. Overall, of 191 unoperated patients with severe AS, 70 (37%) were symptomatic and had an estimated perioperative mortality risk of ≤5%.

Among patients with severe AS who underwent AVR, the median calculated STS perioperative mortality risk was 1.8% (IQR, 1.0 to 3.0). Of 126 unoperated symptomatic patients,
28 (22%) had a calculated operative risk no more than the median calculated risk among patients who underwent AVR (Table 3). Similarly, the median perioperative STS risk of combined mortality and morbidity among operated patients was 13.1% (IQR, 10.0 to 18.2%). Of 126 unoperated symptomatic patients, 25 (20%) had a calculated risk of combined mortality and morbidity no more than the median risk for the operated patients (Table 4).

Rationale for No Intervention
For patients who did not undergo AVR, decisions not to operate were based on several factors that were common across medical institutions (Table 5). The most common reasons included patient comorbidities and perceived prohibitive operative risk, patient declining valve replacement (often associated with assessment of high operative risk), and symptoms attributed to an etiology other than AS. In general, among symptomatic unoperated patients, the calculated perioperative risks tended to be highest among patients who did not undergo surgery because of cited comorbidities (mortality risk, 5.3% [IQR, 2.5 to 7.3%]; mortality and morbidity risk, 27.5% [IQR, 17.3 to 31.8%]) and among patients who declined intervention (mortality risk, 4.5% [IQR, 2.6 to 8.0%]; mortality and morbidity risk, 23.8% [IQR, 18.3 to 29.5%]) compared with patients who were not operated for other reasons (mortality risk, 2.8% [IQR, 1.4 to 4.5%], P=0.006 versus prohibitive operative risk, P=0.02 versus patient refusal; mortality and morbidity risk, 17.1% [IQR, 11.9 to 24.1%], P=0.002 versus prohibitive risk, P=0.009 versus patient refusal). Of 4 patients who died before surgery, 2 presented in cardiogenic shock and 2 died before elective AVR. Notably, there were patients at each institution (10 patients in total, representing 8% of patients with unoperated

28 (22%) had a calculated operative risk no more than the median calculated risk among patients who underwent AVR (Table 3). Similarly, the median perioperative STS risk of combined mortality and morbidity among operated patients was 13.1% (IQR, 10.0 to 18.2%). Of 126 unoperated symptomatic patients, 25 (20%) had a calculated risk of combined mortality and morbidity no more than the median risk for the operated patients (Table 4).

**Table 4. Calculated Risk of Perioperative Combined Mortality and Morbidity for Operated and Unoperated Patients (Median [IQR])**

<table>
<thead>
<tr>
<th></th>
<th>All Sites</th>
<th>University</th>
<th>VA</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients, %</td>
<td>15.1 (11.1–22.6)</td>
<td>13.1 (10.2–19.1)</td>
<td>14.99 (10.7–19.0)</td>
<td>17.9 (13.0–26.6)</td>
</tr>
<tr>
<td>Operated, %</td>
<td>13.1 (10.0–18.2)</td>
<td>12.0 (9.6–15.1) %</td>
<td>12.8 (9.7–17.2) %</td>
<td>15.4 (12.1–21.3)</td>
</tr>
<tr>
<td>Unoperated, %</td>
<td>17.8 (12.1–27.4)</td>
<td>16.5 (11.4–26.6)</td>
<td>15.5 (11.2–19.2)</td>
<td>21.6 (14.0–29.2)</td>
</tr>
<tr>
<td>P (operated vs unoperated)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.08</td>
<td>0.001</td>
</tr>
<tr>
<td>Unoperated symptomatic, %</td>
<td>22.5 (15.5–30.3)</td>
<td>18.5 (11.8–29.4)</td>
<td>19.2 (16.3–30.0)</td>
<td>27.0 (19.1–30.9)</td>
</tr>
<tr>
<td>Unoperated asymptomatic, %</td>
<td>13.3 (10.5–16.6)</td>
<td>13.3 (10.5–18.2)</td>
<td>11.7 (10.7–14.9)</td>
<td>13.5 (10.2–16.3)</td>
</tr>
<tr>
<td>P (symptomatic vs asymptomatic)</td>
<td>&lt;0.001</td>
<td>0.04</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Symptomatic unoperated and risk &lt;AVR median, n/N (%)</td>
<td>25/126 (20)</td>
<td>14/53 (26)</td>
<td>2/20 (10)</td>
<td>7/53 (13)</td>
</tr>
</tbody>
</table>

Data are presented as median (IQR).
severe AS) in whom the diagnosis of severe AS, although reported on the echocardiogram, was not recognized during subsequent medical interactions.

Among 23 unoperated symptomatic patients in whom symptoms were attributed to an etiology other than AS, exercise stress testing to evaluate the impact of AS on cardiac function was performed in only 6 (26%). The use of exercise stress testing was not significantly different between settings (1 of 11 [9%] at the university, 2 of 4 [50%] patients at the VA, and 3 of 8 [38%] in the private practice setting).

Dementia did not appear to play a major role in decisions not to refer for intervention. Among all unoperated patients, 10 had a history of dementia, including 4 asymptomatic patients and 6 with symptoms.

Impact of Advanced Age
Among all 369 patients with severe AS, 102 (27.6%) were ≥80 years of age; including 27 of 178 (15.2%) patients who underwent AVR and 75 of 191 (39.3%, P<0.0001) who were unoperated. Age ≥80 years was associated with a higher predicted perioperative mortality risk for both operated (4.4% [IQR, 3.2 to 5.5%] versus 1.3% [IQR, 0.9 to 2.2%], P<0.001) and unoperated patients (5.4% [IQR, 3.3 to 7.6%] versus 1.7% [IQR, 1.1 to 2.8%], P<0.001). In addition, the calculated perioperative mortality risk among patients ≥80 years was higher for unoperated than for operated patients (P=0.04).

Follow-Up
Average follow-up duration for unoperated patients was 16.7±14.1 months (range, 0 to 46 months). A total of 54 unoperated patients died, including 7 asymptomatic patients and 47 symptomatic patients. Survival is shown in Figure 3.

Discussion
AVR currently is the only effective treatment for severe symptomatic AS.2-4,5 Despite this, some patients with indications for surgery do not undergo intervention. Advanced age previously has been noted to be associated with lower rates of intervention.6,9-11 However, because of demonstrated benefit even among elderly patients,9-11 current2-5 and recent guidelines2 suggest that consideration for surgery should not be denied based solely on advanced age.

Table 5. Rationale for Decisions to Not Perform AVR in Symptomatic Patients With Severe AS

<table>
<thead>
<tr>
<th></th>
<th>All Sites (n=126)</th>
<th>University (n=53)</th>
<th>VA (n=20)</th>
<th>Private (n=53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidities/operative risk</td>
<td>61 (48)</td>
<td>30 (57)</td>
<td>8 (40)</td>
<td>23 (43)</td>
</tr>
<tr>
<td>Patient declined</td>
<td>24 (19)</td>
<td>2 (4)</td>
<td>5 (25)</td>
<td>17 (32)</td>
</tr>
<tr>
<td>Symptoms not from AS</td>
<td>24 (19)</td>
<td>11 (21)</td>
<td>5 (25)</td>
<td>8 (15)</td>
</tr>
<tr>
<td>Subvalvular stenosis</td>
<td>3 (2)</td>
<td>3 (6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Died before surgery</td>
<td>4 (3)</td>
<td>4 (8)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AS not recognized</td>
<td>10 (8)</td>
<td>3 (6)</td>
<td>2 (10)</td>
<td>5 (9)</td>
</tr>
</tbody>
</table>

Data are presented as n (%).

Figure 3. Kaplan–Meier survival of unoperated patients with severe aortic stenosis. Survival of unoperated symptomatic (solid line) and asymptomatic (dashed line) patients reveals high mortality among unoperated symptomatic patients.

Current Findings
In the present study, approximately half of patients with severe AS did not undergo intervention, and two thirds of unoperated patients were symptomatic. As such, 1 in 3 patients with severe AS had symptoms but did not undergo intervention. Rather than revealing that a handful of patients did not undergo AVR in association with extremes of age or other extenuating circumstances, this study suggests that symptomatic patients with severe AS frequently do not undergo intervention. The associated clinical implications are substantial, because prognosis without intervention is dismal (in this study, 12-month survival was only 66% among unoperated symptomatic patients), whereas AVR is associated with both symptomatic improvement and improved survival.

Practice Setting
The finding of relatively low rates of intervention for patients with AS could be interpreted as an institutional problem related to quality of care. In the present study, however, intervention rates were investigated in multiple practice settings. The participating sites are major referral institutions, providing essentially all access to cardiac surgery within Washtenaw County in southeastern Michigan. The diversity of sites and similar findings across practice locations suggest that rates of intervention for AS are not specific to a single institution or to a specific type of practice.

Patient characteristics were predominantly similar between study sites, with minor differences noted, including an exclusively male population at the VA and relatively older patients in the private setting. These differences appear to reflect inherent differences in the populations served by the respective medical centers. The differences do not appear to detract from the common finding of low rates of intervention at all study sites.
Factors Affecting Decision-Making

Among symptomatic patients who did not undergo surgery, comorbidities with associated concern for prohibitive operative risk was cited most often, followed by the patient’s decision not to undergo evaluation for AVR. In many ways, these 2 groups were similar. In one group, physicians recommended no intervention based on an assessment of prohibitive risk; and in the other, the patient turned down surgery after having been presented with an assessment of prohibitive risk. Combined, these represented 67% of all unoperated symptomatic patients.

Although some unoperated patients had very high operative risks, many symptomatic patients who did not undergo surgery appear to have had an acceptable operative risk based on objective measures. Specifically, among symptomatic patients who did not undergo AVR, 56% had an objectively calculated perioperative mortality risk ±5%, and in 22% the calculated mortality risk was less than the median risk for patients who underwent AVR. These findings suggest that subjective means of assessing operative risk may be unreliable, at a cost of denying consideration for intervention to patients who are legitimate candidates and who might benefit from surgery. This is supported by a recent report, noting that 24% of patients referred for percutaneous AVR for inoperable severe symptomatic AS ultimately underwent surgical AVR after objective assessment at the referral center.

Previously published reports have demonstrated that advanced age is an important factor in denying surgery for severe AS. Advanced age predictably was associated with a higher estimated operative risk among both operated an unoperated patients. However, although the calculated operative risk was higher among unoperated than among operated patients ≥80 years of age, the magnitude of the difference (median mortality risk 4.4% versus 5.4%) was relatively small and did not appear to be prohibitive. Because advanced age was frequently cited among patients who were not referred for surgery owing to comorbidities and anticipated high operative risk, this observation supports previous findings that advanced age plays a disproportionate role in physicians’ subjective assessment of risk.

Study Limitations

This was a retrospective observational study. However, patients with severe AS were identified in a consistent way that is compatible with guideline recommendations for the quantitation of AS. Management and decision-making were evaluated by means of careful chart review, and rationale for decisions typically was apparent. Patient refusal as a reason that AVR was not performed was taken from review of medical records, and was not confirmed by patient interview.

Symptomatic status was not reassessed during follow-up. However, the natural history of severe asymptomatic AS has been previously defined; existing literature supports that some asymptomatic patients who died during follow-up likely first developed symptoms.

A variety of schemes are available to calculate perioperative risk. The STS risk calculator was used because it has been shown to provide the most accurate assessment of perioperative and long-term mortality for the highest risk patients undergoing AVR. However, any scheme that attempts to quantify operative risk may not fully account for pertinent issues that impact the management of an individual patient. As such, some unoperated patients legitimately may not have been reasonable surgical candidates despite relatively low calculated perioperative risk.

Future Directions

These data suggest that many patients who could benefit from surgical intervention for symptomatic severe AS do not undergo evaluation for AVR. Efforts aimed at education regarding the benefits associated with intervention may be helpful. Many patients were not referred for surgical evaluation because of perceived prohibitive comorbidities; the finding that subjective assessment of operative risk tended to frequently and grossly overestimate objectively estimated risk suggests that education is necessary regarding realistic risks associated with cardiac surgical procedures in the modern era. Because 95% of unoperated patients had been evaluated by a cardiovascular medicine specialist, education appears to be required beyond the primary care setting.

In a small but not inconsequential number of cases, the echocardiographic diagnosis of severe AS was not acknowledged in other clinical medical records. Although this could simply reflect a lack of documentation of an acknowledged medical issue, it also could reflect problems with communication from echocardiography laboratories to clinical practice.

The results of this study are especially poignant in an era in which increasing scrutiny is placed on ensuring the quality of medical care. The treatment of some common medical conditions is followed by government oversight agencies, including the use of βadrenergic antagonists in patients with heart failure and in patients having suffered acute myocardial infarction. Although severe symptomatic AS is relatively common and has very discrete options for appropriate management, standard therapy was not used in many patients. It is presumed that patient outcomes could improve if more patients underwent an appropriate evaluation for intervention.

Conclusion

One third of patients with severe AS are symptomatic but do not undergo AVR, with similar findings in multiple tertiary care environments. For most unoperated patients, objectively calculated operative risks did not appear prohibitive; for many patients, calculated risks were lower than those for patients who underwent AVR. Despite this, a minority of unoperated patients were referred for surgical consultation. Some patients with severe symptomatic AS may be inappropriately denied access to potentially life-saving therapy.

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Disclosures

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References
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