VETERANS HEALTH ADMINISTRATION
OFFICE OF PATIENT CARE SERVICES
TECHNOLOGY ASSESSMENT PROGRAM

Brief Overview:

Guidance for Screening for Abdominal Aortic Aneurysms in Veterans Health Administration

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TECHNOLOGY ASSESSMENT PROGRAM

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BRIEF OVERVIEW:
Guidance for Screening for Abdominal Aortic Aneurysms in Veterans Health Administration (VHA)

PURPOSE

This document provides evidence-based guidance on implementing updated US Preventive Services Task Force (USPSTF) recommendations on screening for abdominal aortic aneurysms (AAA) in VHA. The guidance is intended to help clinicians identify patients who are candidates for surgical intervention of AAA and are therefore suitable for screening. The ultimate goal is to improve the effectiveness of patient care and optimize patient outcomes.

To the extent that this report identifies new clinical trial information on the effectiveness of endovascular repair of AAA, this document further updates a 1998 VA Technology Assessment Program (VATAP) report entitled: *"Endovascularly Placed Grafts for Infrarenal Abdominal Aortic Aneurysms: A Systematic Review of Published Studies of Effectiveness"* (Bertram 1998).

BACKGROUND

AAA, with its high propensity to rupture and associated mortality, is a significant health problem in the United States. As most AAAs are asymptomatic until rupture, ultrasound screening has been suggested to detect asymptomatic AAA prior to rupture and reduce the associated mortality.

Patients with asymptomatic AAA and a positive ultrasound screening test are managed with either surveillance or prophylactic surgical repair. The choice between surveillance and surgery should take into account the individual patient's estimate of rupture risk under observation, operative risk of repair, life expectancy, and patient preferences (Schermerhorn 2005). Targeted ultrasound screening will help focus resources on those most at risk, and identify who will benefit from surgical intervention.

Evidence reviews found that screening will benefit populations with a reasonably high probability of having an AAA that is large enough (≥ 5.5 cm diameter) or will become large enough to benefit from surgery and for those who have a reasonable life expectancy. Populations most at risk for AAA are males over the age of 65 with a positive smoking history and a first degree family history of AAA requiring surgical repair (Schermerhorn 2005; AHRQ 2005).

In February 2005, the USPSTF issued an updated recommendation statement on screening for AAA, recommending a one-time screening by ultrasonography in men aged 65 to 75 years who have ever smoked (a grade **B** recommendation[1]). The Task

[1] The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms*. Source: http://www.ahrq.gov/clinic/3rduspstf/ratings.htm#brec accessed October 18, 2005.

Force made no recommendation for or against screening for AAA in men age 65 to 75 years who have never smoked (a grade **C** recommendation[2]). The Task Force recommended against routine screening for AAA in women (a grade **D** recommendation[3]), although individualization of care is required in special circumstances; for example, in the healthy female smoker age 65 or older who has a history of first-degree relatives with AAA that required surgical intervention (USPSTF 2005).

The recommendation in favor of screening men aged 65 to 75 years who have ever smoked was based on the finding of sound evidence that surgical repair of large aneurysms (≥ 5.5 cm) leads to decreased AAA-specific mortality. There was good evidence that abdominal ultrasonography, performed in a setting with adequate quality assurance, is an accurate screening test for AAA. The net benefits (population-level benefits minus potential harms) were judged to be moderate in magnitude because of evidence of important harms of screening and early treatment, which included an increased number of surgeries with associated clinically significant morbidity and mortality.

Peri-operative mortality for open surgical repair of AAA is 4% to 5%, and is associated with significant adverse outcomes such as cardiac and pulmonary complications and an increased risk for impotence; open repair is associated with better outcomes when performed by specialty surgeons in high-volume hospitals (USPSTF 2005). Endovascular repair (EVAR) was introduced for patients with poor health status who are considered unfit for major surgery, and is being investigated as an alternative to open repair of AAA (Prinssen 2004; Greenhalgh 2004). While short term improvements in mortality and morbidity have been reported, the long-term effectiveness of EVAR compared to open repair to reduce AAA rupture and mortality is being studied. These trial results may provide a better understanding of the net benefits and harms for patients undergoing EVAR, and assist in defining the population best suited for screening.

Implications for VHA

Implementing the recommendation for a one-time screening for AAA of men aged 65 to 75 years who have ever smoked in VHA has significant resource implications for primary care, radiological, and surgical services. Estimates from the Survey of Healthcare Experiences of Patients (SHEP) show approximately 25-30% of men in VHA are in the target age group (aged 65-75) and, of those, about 80-85% are ever smokers. Thus, roughly 1 million men might currently be eligible for AAA screening. *Further defining which patients could be considered candidates for operative repair and thus suitable candidates for screening may help guide providers in their screening recommendations and may help distribute the resources of radiology and surgery appropriately.*

[2] The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation*. Source: http://www.ahrq.gov/clinic/3rduspstf/ratings.htm#brec accessed October 18, 2005.

[3] The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits*. Source: http://www.ahrq.gov/clinic/3rduspstf/ratings.htm#brec accessed October 18, 2005.

METHODS

The Chief Patient Care Services Officer (CPCSO) requested that a VHA working group with expertise in the management of patients with AAA develop additional guidance to assist the field in identifying patients who appear unfit for surgical intervention and, therefore, should not be screened. The working group consisted of:

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Operative risk stratification schemes will help identify candidates with poor surgical risk. Since publication of the latest USPSTF guidance on screening AAA, new trial data have emerged on the role of EVAR versus open repair, which may alter the risk estimates and judgments about elective surgical treatment of AAA and, ultimately, the choice of patients who should be targeted for ultrasound screening. Therefore, the working group sought to:

1. Clarify the role of EVAR vs. open repair;
2. Identify operative risk stratification schemes suitable for application to AAA screening to identify patients with poor surgical risk in VHA.

RESULTS

EVAR vs. open repair

Both the EVAR (Greenhalgh 2004) and DREAM (Prinssen 2004) RCTs have shown improved short-term mortality and complication rates with EVAR compared to open surgical repair. Since the USPSTF recommendations were published, further results of trials of EVAR have been published. EVAR trial 1 (2005) was a randomized controlled trial of 1082 patients aged 60 years and older with aneurysms of at least 5.5 cm in diameter. Patients who were anatomically suitable for EVAR and fit for open repair were randomized to either EVAR or open repair.

The primary endpoint was all-cause mortality, with secondary endpoints of aneurysm-related mortality, health-related quality of life (HRQL), post-operative complications, and hospital costs. Four years after randomization, all-cause mortality was similar in the two groups (about 28%; hazard ratio [HR] 0.90, 95% confidence interval [CI] 0.69-1.18), but there was a persistent reduction in aneurysm-related deaths in the EVAR group (4% vs. 7%; HR 0.55, 95% CI 0.31-0.96). The proportion of patients with post-operative complications within 4 years was 41% in the EVAR group and 9% in the open repair group (HR 4.9, 95% CI 3.5-6.8). After 12 months, there was a negligible difference in the HRQL between the two groups. Mean hospital costs were higher for patients in the EVAR group.

The authors concluded that, compared with open repair, EVAR offered no advantage with respect to all-cause mortality and HRQL, was more expensive, and led to a greater number of complications and re-interventions. However, EVAR did result in a 3% better aneurysm-related survival.

EVAR trial 2 (2005) was conducted similarly, randomizing 338 patients aged 60 years and older with aneurysms of at least 5.5 cm in diameter and who were not candidates for open repair to one of two arms: EVAR or no surgical intervention. The 30-day operative mortality in the EVAR group was 9% and the no-intervention group had a rupture rate of 9.0 per 100 person years. After an average follow-up period of 3.3 years, overall mortality was 64%, with no significant difference between the two groups in all-cause mortality or aneurysm-specific mortality. Mean hospital costs were higher in the EVAR group.

Thus, this study of patients not suitable for open repair showed a high 30-day operative mortality with EVAR and no long-term improvement in survival. Patients who underwent EVAR required continued surveillance and re-intervention, at substantially increased cost.

Guidance for assessing surgical fitness of open repair

The VATAP sought to identify guidance for assessment of patient fitness for open repair, relying heavily on guidance used in recently published RCTs and on reports on the management of AAA by AHRQ (2005), Schermerhorn (2005) and Brewster (2003) to inform the working group, rather than undertaking a comprehensive systematic review. Two studies in addition to the EVAR trial guidance were identified and are summarized in Table 1.

SUMMARY OF FINDINGS

The recent EVAR trial results helped define the role of open repair vs. EVAR for AAA, and therefore informed advice on who may be screened for AAA. *For patients unsuitable for open repair, EVAR does not offer an advantage over no intervention. For patients suitable for either type of surgery, the results are mixed; there is no clear advantage of EVAR over open repair.*

Guidance on selecting patients suitable for surgical repair from the EVAR trial (Brown 2004), which represents the best available evidence for defining the role of EVAR vs. open repair of elective AAA, provides practical clinical guidance to assist the field in decision making regarding who may be excluded from screening for AAA:

Patients with the following risk factors may not be suitable candidates for open repair:

Cardiac status:

- MI within last 3 months
- Onset of angina within the last 3 months
- Unstable angina at night or at rest
- Severe valve disease
- Significant arrhythmia
- Uncontrolled congestive heart failure

Respiratory status:
- Unable to walk up a flight of stairs without shortness of breath
- FEV_1 < 1.0 L
- PO_2 < 60 mm Hg
- PCO_2 > 50 mm Hg

Renal status:
- Serum creatinine > 200 μmol/L (2.3 mg/dl)

RECOMMENDATIONS

The working group recommends that:

1. VHA adopt the USPSTF recommendation to provide one-time AAA screening for men aged 65 to 75 years who have ever smoked using ultrasonography.
2. VHA clinicians should take into consideration the risk factors adapted from the EVAR trial when deciding whether to recommend screening for individual patients.
3. VHA clinicians may consider screening men aged 65 to 75 years who have never smoked for AAA, depending on individual decision-making shared by providers and patients.
4. Generally VHA clinicians would not recommend routine screening for AAA to women, but individual risk factors, such as a history of first-degree relatives with AAA that required surgical intervention, may be considered.

Table 1. Guidance for Establishing Patient Fitness for Open Elective Repair of AAA

	Brown (2004)	Steyerberg (1998)	Brewster (2003)	
Description	**EVAR trial guidance for fitness for open repair**	**Meta-analysis of risk factors for operative mortality after elective AAA repair**	**Consensus of Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery: Operative mortality risk of open AAA repair**	
			Average risk	**High risk**
Cardiac Status	Not suitable for open repair: • MI within last 3 months • Onset of angina within last 3 months • Unstable angina at night or at rest • Severe valve disease • Significant arrhythmia • Uncontrolled congestive cardiac failure	• Presence of CHF (OR=2.3, 95% CI 1.1-5.2) • Presence of EKG ischemia (ST depression > 2mm) (OR=2.2, 95% CI 1.0-5.1)	• Stable coronary disease • Remote MI • EF > 35%	• Significant coronary disease • Recent MI • Frequent angina • CHF • EF < 25%
Respiratory Status	Open repair would not be suitable for the following patients: • Unable to walk up flight of stairs without shortness of breath (even with some angina on effort) • FEV_1 <1.0 L/sec • PO_2 < 8.0KPa (60mmHg) • PCO_2 > 6.5 KPa (49 mmHg)	Pulmonary dysfunction (OR=1.9, 95% CI 1.0-3.8)	Mild COPD	• Limiting COPD • Dyspnea at rest • O2 dependency • FEV_1 <1.0 L/sec
Renal Status	Open repair might not be recommended for patients presenting with serum creatinine levels > 200µmol/L	Creatinine > 1.8mg/dL (OR=3.3, 95% CI 1.5-7.5)	Creatinine 2.0-3.0	Creatinine > 3
Age		Older age-by decade (OR=1.5, 95% CI 1.2-1.8)	Age 70-80 yrs	Age > 80 yrs
Gender		Female gender (OR=1.5, 95% CI 0.7-3.0)		
Activity level			Active	Inactive Poor stamina
Anticipated operative mortality			Anticipated operative mortality, 3%-7%	Anticipated operative mortality, at least 5%-10% Each comorbid condition adds approx. 3%-5% mortality risk
Other			Adverse anatomy or AAA characteristics	Liver disease

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TECHNOLOGY ASSESSMENT PROGRAM

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