Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Early thrombus removal strategies for acute deep venous thrombosis: clinical practice guidelines for the Society for Vascular Surgery and the American Venous Forum.

Bibliographic Source(s)

Meissner MH, Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Lohr JM, McLafferty RB, Murad MH, Padberg F, Pappas P, Raffetto JD, Wakefield TW, Society for Vascular Surgery, American Venous Forum. Early thrombus removal strategies for acute deep venous thrombosis: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2012 May;55(5):1449-62. [107 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions of the strength of the recommendations (Grade 1 or 2) and quality of the evidence (Level A–C) are provided at the end of the "Major Recommendations" field.

Precision in the Diagnosis of Deep Venous Thrombosis (DVT)

The Guideline Committee recommends use of precise anatomic terminology to characterize the most proximal extent of venous thrombosis as involving the iliofemoral veins, with or without extension into the inferior vena cava; the femoropopliteal veins; or isolated to the calf veins in preference to simple characterization of a thrombus as proximal or distal (Grade 1A).

If iliofemoral venous thrombosis is suspected but not confirmed using standard diagnostic modalities such as venous ultrasound imaging, the Guideline Committee recommends the use of adjunctive imaging modalities, such as computed tomography venography or magnetic resonance venography to characterize the most proximal thrombus extent (Grade 1C).

Indications for Early Thrombus Removal

The Guideline Committee suggests a strategy of early thrombus removal in selected patients meeting the following criteria (a) a first episode of acute iliofemoral deep venous thrombosis, (b) symptoms <14 days in duration, (c) a low risk of bleeding, and (d) ambulatory with good functional

capacity and an acceptable life expectancy (Grade 2C).

The Guideline Committee recommends early thrombus removal strategies as the treatment of choice in patients with limb-threatening venous ischemia due to iliofemoral deep venous thrombosis with or without associated femoropopliteal venous thrombosis (phlegmasia cerulea dolens) (Grade 1A).

The Guideline Committee recommends that patients with isolated femoropopliteal deep venous thrombosis be managed with conventional anticoagulation therapy because there is currently insufficient evidence to support early thrombus removal strategies in this patient population (Grade 1C).

Techniques for Early Thrombus Removal

The Guideline Committee suggests percutaneous catheter-based techniques (pharmacologic or pharmacomechanical) as first-line therapy for early thrombus removal in patients meeting the criteria in the first recommendation under "Indications for Early Thrombus Removal" (Grade 2C).

The Guideline Committee suggests a strategy of pharmacomechanical thrombolysis be considered over catheter-directed pharmacologic thrombolysis alone if expertise and resources are available (Grade 2C).

The Guideline Committee suggests open surgical venous thrombectomy in selected patients who are candidates for anticoagulation but in whom thrombolytic therapy is contraindicated (Grade 2C).

Periprocedural Inferior Vena Cava Filters

The Guideline Committee recommends against routine use of inferior vena cava filters (permanent or temporary) in conjunction with catheter-directed pharmacologic thrombolysis of the iliofemoral venous segments (Grade 1C).

The Guideline Committee suggests that the relative risks vs benefits of periprocedural retrievable inferior vena cava filter placement be considered in patients undergoing pharmacomechanical thrombolysis and those with thrombus extending into the inferior vena cava or having markedly limited cardiopulmonary reserve (Grade 2C).

Adjunctive Use of Venous Stents

The Guideline Committee recommends the use of self-expanding metallic stents for treatment of chronic iliocaval compressive or obstructive lesions that are uncovered by any of the thrombus removal strategies (Grade 1C).

The Guideline Committee suggests that stents not be used in the femoral and popliteal veins (Grade 2C).

Early Thrombus Removal Strategies as an Adjunct to Conventional Management

The Guideline Committee recommends that patients managed with early thrombus removal be treated with a standard course of conventional anticoagulation after the procedure (Grade 1A).

The Guideline Committee recommends that all patients be treated with knee-high compression stockings (30 to 40 mm Hg) for at least 2 years after the procedure (Grade 1C).

Definitions:

Quality of Evidence

- Grade A, or high-quality evidence, usually comes from well-executed randomized trials yielding consistent results, and occasionally, observational studies with large effects.
- Grade B, or moderate-quality evidence, comes from randomized clinical trials with important limitations, inconsistent randomized trials, and strong observational studies.
- Grade C, or low-quality evidence, includes flawed randomized trials and most observational studies as well as data from case reports, descriptive studies, and expert opinion.

Strength of Recommendation

- Grade 1 recommendations ("strong") are those in which the benefits of an intervention clearly outweigh its risk and burdens. All well-informed patients would choose such a treatment, and the physician can securely recommend it without a detailed knowledge of the underlying data.
- Grade 2 recommendations ("weak") are weaker and reflect therapies where the benefits and risks are uncertain or are more closely

balanced. For such interventions, patients may choose different options based on their underlying values.

In accordance with the American College of Chest Physicians (ACCP) guidelines for the antithrombotic treatment of venous thromboembolic disease, the Guideline Committee has adopted the language of "recommending" the use of strong Grade 1 guidelines and "suggesting" the use of weaker Grade 2 guidelines.

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Approach to Treatment Recommendations

Recommendation	Benefit vs Risk	Quality of Evidence	Comment
1A	Clear	High: Consistent results from RCTs or observational studies with large effects	Strong recommendation, generalizable
1B	Clear	Moderate: RCTs with limitations and very strong observational studies	Strong recommendation; may change with further research
1C	Clear	Low: Observational studies Very low: Case series, descriptive reports, expert opinion	Intermediate recommendation; likely to change with further research
2A	Balanced or unclear	High: Consistent results from RCTs or observational studies with large effects	Intermediate recommendation: May vary with patient values
2B	Balanced or unclear	Moderate: RCTs with limitations and very strong observational studies	Weak recommendation: May vary with patient values
2C	Balanced or unclear	Low: Observational studies Very low: Case series, descriptive reports, expert opinion	Weak recommendation: Alternative treatments may be equally valid

RCT = randomized controlled trial

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Acute deep venous thrombosis (DVT)

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Hematology

Internal Medicine

Radiology

Surgery

Intended Users

Physicians

Guideline Objective(s)

To develop evidence-based practice guidelines for early thrombus removal strategies, including catheter-directed pharmacologic thrombolysis, pharmacomechanical thrombolysis, and surgical thrombectomy

Target Population

Patients with or suspected of having acute deep venous thrombosis (DVT)

Interventions and Practices Considered

Diagnosis

1. Use of precise anatomic terminology to characterize the most proximal extent of venous thrombosis
2. Venous ultrasound imaging
3. Adjunctive imaging modalities such as computed tomography venography or magnetic resonance venography

Treatment/Management

1. Patient selection: criteria for early thrombosis removal
2. Percutaneous catheter-based techniques (pharmacologic or pharmacomechanical) for early thrombus removal
3. Open surgical venous thrombectomy
4. Use of inferior vena cava filters (permanent or temporary) in conjunction with catheter-directed pharmacologic thrombolysis (not recommended routinely)
5. Adjunctive use of venous stents
6. Standard course of conventional anticoagulation after the early thrombus removal procedure
7. Use of knee-high compression stocking (30 to 40 mm Hg)

Major Outcomes Considered

- Death
- Pulmonary embolism
- Local complications
- Hemorrhagic complications
- Postthrombotic syndrome
- Pain
- Quality of life
- Surrogate markers of venous function, including valve competence and patency

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse: The committee commissioned a systematic review and meta-analysis from the Knowledge and Encounter Research Unit, Mayo Clinic, Rochester to identify and summarize the best available evidence about the efficacy of catheter-directed thrombolysis, surgical thrombectomy, and systemic anticoagulation for the treatment of iliofemoral deep venous thrombosis (DVT) (see the "Availability of Companion Documents" field).

Eligibility Criteria

Eligible studies were randomized clinical trials and cohort studies that enrolled participants with acute iliofemoral DVT. To allow for the comparative effectiveness of these treatments, included studies had to enroll patients who were treated with at least two of the following three treatments: surgical thrombectomy, catheter-directed thrombolysis, or conservative management with traditional anticoagulation. Reviewers included studies that measured the outcomes of interest (death, pulmonary embolism, local complications, hemorrhagic complications, postthrombotic syndrome, pain, and quality of life). Data about the surrogate outcomes of venous valve competency and vein patency were also collected. Studies were included regardless of their language, sample size, type of thrombolytic used, surgical technique, or duration of patient follow-up. Single cohort studies (i.e., studies in which all patients received the same treatment without concurrent comparison groups) were excluded. Also excluded were studies of systemic thrombolysis, considering the increased risk of bleeding and incomplete thrombolysis known to be associated with this procedure.

Study Identification

An expert reference librarian designed and conducted the electronic search strategy with input from study investigators with expertise in conducting systematic reviews. To identify eligible studies, the reviewers searched electronic databases (MEDLINE, EMBASE, Cochrane CENTRAL, Web of Science, and SCOPUS) through February 2008 and monitored the literature for new publications thereafter. Reference from experts, bibliographies of included trials, and the Institute for Scientific Information (ISI) Science Citation Index for publications that cited included studies were also sought. A combination of subject headings and text words were used to describe the condition and the treatment. The results were limited to clinical trials, meta-analyses, retrospective and prospective studies, and treatment outcomes. The Cochrane Central Register of Clinical Trials was searched using both subject headings and text words. Web of Science and Scopus were searched using text words. The detailed search strategy is available from the authors upon request.

References were uploaded in a web-based software package developed for systematic review data management (SRS, TrialStat Corporation, Ottawa, Ontario Canada). Paired reviewers working independently screened all titles and abstracts for eligibility. References that were deemed potentially relevant were retrieved in full text and uploaded for full text evaluation against eligibility criteria. The chance adjusted inter-reviewer agreement (kappa statistic) about study eligibility was 0.79 (95% confidence interval 0.66-0.93). Disagreements were resolved by consensus (the two reviewers discussed the study and reached a consensus), and when disagreement continued, by arbitration (a third reviewer adjudicated the study).

Number of Source Documents

The reviewers found 22 eligible publications that represented 15 unique studies and 2 systematic reviews. Ten studies compared thrombectomy to systemic anticoagulation and five other studies compared pharmacologic catheter-directed thrombolysis to systemic anticoagulation. Figure 1 in the systematic review companion document (see the "Availability of Companion Documents" field) depicts the search and selection procedures.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Ratings

- Grade A, or high-quality evidence, usually comes from well-executed randomized trials yielding consistent results, and occasionally, observational studies with large effects.
- Grade B, or moderate-quality evidence, comes from randomized clinical trials with important limitations, inconsistent randomized trials, and strong observational studies.
- Grade C, or low-quality evidence, includes flawed randomized trials and most observational studies as well as data from case reports, descriptive studies, and expert opinion.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

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Data Collection

Teams of two reviewers working independently and using a standardized form extracted data from all eligible studies. The reviewers extracted descriptive data (study size, number of patients in each arm, patients' age, thrombophilia risk factors, DVT location, time elapsed between onset of symptoms and intervention, and description of the intervention and control procedure), methodological data (elements of bias protection in randomized trials such as allocation concealment, blinding, and proportions of patients lost to follow-up; and elements of bias protection in observational studies such as the prognostic comparability of the two study groups, ascertainment of exposure and outcome and blinding of outcome assessors), and outcome data (death, pulmonary embolism, local complications, hemorrhagic complications, postthrombotic syndrome, pain, quality of life and surrogate markers of venous function including valve competence and patency). Reviewers attempted to contact authors of all included studies by e-mail to obtain missing data.

Statistical Analysis

Meta-analyses

The reviewers pooled relative risks (RR) for dichotomous outcomes from each study using the DerSimonian-Laird random effects model and estimated the 95% confidence intervals (CI) for each outcome to reflect the uncertainty of point estimates of effect. For continuous outcomes, the weighted effect size and CI were estimated. They used the I^2 statistic, which estimates the percentage of total variation across studies that is due to heterogeneity rather than chance (i.e., the percentage of variability in treatment effects across trials that is not due to chance or random error, but rather due to real differences in study patients, design or interventions). Statistical analysis was conducted using Comprehensive Meta-Analysis, Version 2 (Biostat Inc., 2005, Englewood, New Jersey).

Anticipating that few if any studies would have directly compared catheter-directed thrombolysis and surgical thrombectomy, the reviewers explored Bayesian indirect comparisons to make inferences on the difference of the treatment effects between the two interventions that may not have been compared head-to-head. The reviewers calculated the posterior median with 95% credible intervals (CrI) of relative risks for comparing the treatment effects on outcomes of interest. Bayesian analysis was conducted using WinBUGS, version 1.4.3, Cambridge, United Kingdom (UK).

Subgroup and Sensitivity Analyses

The a priori hypotheses to explore subgroup interactions and explain inconsistency in the direction and magnitude of effect among studies included variation in bias protection measures, patient characteristics (age, whether patients have risk factors for recurrent DVT), duration between the onset of DVT symptoms and delivery of intervention (a week or less vs. more than a week), and the length of study follow up (a year or less vs.

more than a year). The hypothesis of a subgroup effect was tested using a test of interaction. Meta-regression was also conducted to assess the correlation between the effect size and the proportion of patients lost to follow-up, a measure of study quality. In addition, the reviewers conducted a sensitivity analysis excluding studies in which thrombosis was not confined to the iliofemoral segment.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) formed a committee of experts in venous disease to develop evidence-based clinical practice guidelines regarding strategies of early thrombus removal for acute deep vein thrombosis (DVT). The committee commissioned the conduct of a systematic review and meta-analysis of the relevant literature to inform their recommendations (see the "Availability of Companion Documents" field). In contrast to previously published systematic reviews, this review was confined to patients with iliofemoral DVT and excluded systemic and locoregional thrombolytic infusion (e.g., pedal vein infusion) while including surgical thrombectomy. The results of this systematic review forms the basis of these practice guidelines. When necessary, as for pharmacomechanical thrombolysis and inferior vena cava (IVC) filtration, this review was supplemented by less rigorous data, including those from pooled analyses and case series.

The recommendations for early thrombus removal are made according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. According to this system, there are two components to any treatment recommendation: the first is a designation of the strength of the recommendation (strong: 1; or weak: 2) based on the degree of confidence that the recommendation will provide more benefit than harm; the second is an evaluation of the level of evidence (A to C) based on the confidence that the estimate of effect is correct. The strength of a recommendation (1 or 2) reflects the balance of benefits and risks, as well as cost to the health care system (see the "Rating Scheme for the Strength of the Recommendations" field).

In making recommendations, committee members considered the available evidence, patients' values and preferences, availability of surgical expertise, and resource allocation. A systematic process was followed whereby initial guidelines were drafted and submitted, together with the systematic review, to each panel member for comment. Comments were incorporated into the guidelines and resubmitted to the panel members for further revision or acceptance. The process was repeated until there was uniform agreement on the text of the final recommendations. Occasional differences regarding the grade of recommendation were resolved through additional review of the available data, discussion, and formal vote. On adoption of the final manuscript, there was a maximum of one dissenting opinion regarding the grade of two of the recommendations.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

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Recommendation	Benefit vs Risk	Quality of Evidence	Comment
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RCT = randomized controlled trial

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The Document Oversight Committee of the Society for Vascular Surgery (SVS) conducts peer reviews of the guidelines documents. This committee consists of a panel of eight experts not involved in any of the aforementioned steps. Committee members who participated in writing the guidelines manuscript are excused from the review process.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

By restoring venous patency and preserving valvular function, early thrombus removal strategies can potentially decrease postthrombotic morbidity.

Potential Harms

- Competing risks of early thrombus removal include those associated with surgery (surgical thrombectomy) and bleeding (thrombolytic strategies). Systematic review of comparative studies suggests that adverse events are poorly reported overall and that caution is warranted in ensuring patients are appropriately selected.
- The associated risks of catheter-directed thrombolysis include hemorrhage (particularly intracranial), pulmonary embolus (PE), and recurrent

deep vein thrombosis (DVT). Although complications have been poorly reported in comparative trials, some data regarding the bleeding complications associated with catheter-directed thrombolytic therapy are available. Among 473 patients reported in the multicenter National Venous Registry, bleeding complications were reported in 54 (11%), neurologic complications in two (0.4%), PE in six (1%), and death in two (0.4%). Bleeding complications were most common at the venous insertion site (4%) or in the retroperitoneum (1%). Major neurologic complications, including one fatal intracranial hemorrhage and one subdural hematoma, occurred in only two patients (0.4%).

- A systematic review that included trials of systemic and locoregional thrombolysis reported higher rates of bleeding among patients treated with thrombolytic agents (relative risk [RR], 1.73; 95% confidence interval [CI] 1.04-2.88) but no significant differences in mortality (RR, 0.84; 95% CI, 0.29-2.42), pulmonary embolism (RR, 1.23; 95% CI, 0.34-4.45), or intracranial hemorrhage (RR, 1.70; 95% CI, 0.21-13.70). Notably, these authors observed that bleeding complications, which occurred in 10% of thrombolytic patients compared with 8% of patients treated with anticoagulation, tended to decrease over time, perhaps reflecting improved thrombolytic techniques and more rigorous exclusion criteria. Finally, a pooled analysis of 19 studies, largely single-center case series, reported major bleeding in a mean of 8.3% of patients (range, 0%-24%) and rates of symptomatic PE, intracranial hemorrhage, and death of 0.9% (range, 0%-1%), 0.2% (range, 0%-1%), and 0.3% (range, 0%-1%), respectively.
- There are little comparative data evaluating optimal thrombolytic agents, doses of lytic agents and concurrent anticoagulants, and infusion techniques. Streptokinase, although rarely used due to the risks of allergic reactions and bleeding, remains the only thrombolytic agent approved by the United States Food and Drug Administration for the treatment of DVT.
- In recommending the thrombolytic techniques over surgical thrombectomy in patients who are candidates for either approach, a higher value is placed on avoiding the more invasive procedure and potential surgical complications than on unknown differences in bleeding rates. However, given the more invasive nature, the limited experience of most surgeons, and the potentially greater risk of complications with surgical thrombectomy, the weight of the evidence would seem to favor percutaneous thrombolytic approaches over surgical thrombectomy in patients without contraindications to thrombolytic agents.
- Although heparin is effective in cancer-associated thrombosis, institution of warfarin may also lead to venous gangrene and should be approached with caution.

Contraindications

Contraindications

Contraindications to thrombolytic therapy include active internal bleeding; recent cerebrovascular accident or intracranial surgery, trauma, or tumor; recent serious gastrointestinal bleeding; major trauma or surgery ≤10 days; severe uncontrolled hypertension; pregnancy; endocarditis; intracardiac thrombus; known right-to-left shunt; coagulopathy, thrombocytopenia, or absolute contraindications to anticoagulation; suspected septic thrombus; and allergy to thrombolytic agents. Although most contraindications can be identified on routine clinical assessment, some have suggested brain imaging before thrombolysis in patients with malignancies known to metastasize to the central nervous system.

Qualifying Statements

Qualifying Statements

Evidence-based medicine has been defined as "the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients." This specifically involves integrating clinical expertise, the patient's individual situation and preferences, and the best available clinical evidence. The guidelines of the Society for Vascular Surgery (SVS) and American Venous Forum (AVF) should be interpreted as a guide to be applied in the context of clinical judgment rather than as a rigid mandate. Furthermore, there are many aspects of early thrombus removal strategies for which little rigorous data exist and evidence-based guidelines are impractical at the present time. Clinical judgment is of the utmost importance in such situations.

Despite the challenges and inconsistent availability of high-quality evidence, SVS maintains its effort to summarize, synthesize, and present all the available evidence, along with clear clinical practice recommendations, to help surgeons and their patients in decision making. Although the SVS uses state-of-the-art approaches, such as Grading of Recommendations, Assessment, Development and Evaluation framework (GRADE), innovations are needed to improve the quality of evidence in the field and to improve the clarity and usefulness of these guidelines, which will lead to increased confidence in the advice vascular surgeons provide to their patients. Given the limited quality of the evidence, the issues with generalizability, and the importance of patient values, practice guidelines should not be regarded as definitive or prescriptive. Consistent with the tenets of evidence-based medicine, they should be used to inform clinical decision making in the context of

the physician's clinical expertise and the patient's underlying values and preferences.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Safety

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Meissner MH, Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Lohr JM, McLafferty RB, Murad MH, Padberg F, Pappas P, Raffetto JD, Wakefield TW, Society for Vascular Surgery, American Venous Forum. Early thrombus removal strategies for acute deep venous thrombosis: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2012 May;55(5):1449-62. [107 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 May

Guideline Developer(s)

Society for Vascular Surgery - Medical Specialty Society

Source(s) of Funding

Guideline Committee

Venous Guidelines Committee of the Society for Vascular Surgery/American Venous Forum

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Committee members are required to provide a detailed, explicit description of their financial and intellectual conflicts of interest, consistent with the policies of the *Journal of Vascular Surgery*. Additional measures used to manage conflicts of interest include the multidisciplinary structure of guideline committees and the involvement of a methodology group in the evidence synthesis and guidelines integration.

Author conflict of interest: none.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Journal of Vascular Surgery Web site .

Availability of Companion Documents

The following are available:

- Casey ET, Murad MH, Zumeta Garcia M, Elamin MB, Qian S, Erwin PJ, Montori VM, Gloviczki P, Meissner M. Treatment of acute iliofemoral deep vein thrombosis. J Vasc Surg. 2012 May;55:1463-73. Electronic copies: Available from the Journal of Vascular Surgery Web site .
- Murad MH, Montori VM, Sidawy AN, Ascher E, Meissner MH, Gloviczki P. Guideline methodology of the Society for Vascular Surgery including the experience with the GRADE framework. J Vasc Surg. 2011 May;53:1375-80. Electronic copies: Available from the Journal of Vascular Surgery Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on October 17, 2014. The information was verified by the guideline developer on November 18, 2014.

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