Change Healthcare Clinical Evidence Classification

References cited in the clinical content are classified according to the type of evidence presented. The class ratings, I through V, are intended to provide a classification of the evidence but are not necessarily hierarchical. Classifications appear in parentheses at the end of each reference. References followed by an (NC) are not classified; examples include pre-published research or information from government, manufacturer, laboratory, or patient education websites.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Type of Evidence</th>
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<tbody>
<tr>
<td>Class I</td>
<td>Meta-analysis, technology assessment, or systematic review</td>
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<tr>
<td>Class II</td>
<td>Randomized controlled trial</td>
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<td>Class III</td>
<td>Observational or epidemiologic study</td>
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<tr>
<td>Class IV</td>
<td>Evidence-based guideline</td>
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<tr>
<td>Class V</td>
<td>Expert opinion, panel consensus, literature review, text or reference book,</td>
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<td></td>
<td>descriptive study, case report, or case series</td>
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Class I

Class I sources synthesize the results of multiple studies. When quantitative synthesis is possible, meta-analyses can provide a more accurate estimate of the effect or association size than individual smaller studies can. A Class I study that finds insufficient evidence to support or refute an intervention (due to a lack of appropriate primary research) is inconclusive. A potential weakness of Class I studies is that they may only assess published research, potentially leaving their findings vulnerable to publication bias.
Class II
A randomized controlled trial (RCT) is an experimental study design in which subjects are randomly assigned to an intervention or a control group. An RCT is the gold standard for testing cause and effect relationships. Intention-to-treat analysis should be performed to account for missing data points.

Class III
Observational or epidemiologic studies can suggest an association between events or findings. These associations cannot be used to establish causality. Cross-sectional, cohort, and case-control studies are all used to identify possible risk factors. Cross-sectional studies are also used to determine the prevalence of a condition. Cohort studies are used to study incidence, the natural history of a condition, prognosis after a specific exposure, and associated harms. Nonrandomized controlled trials are sometimes used when randomization is impossible or unethical.

Class IV
Evidence-based guidelines are systematically developed recommendations for clinical practice. Evidence-based guidelines identify the methodology used to gather the evidence on which the recommendations are based. Usually, a grading system for both the quality of the evidence and the strength of the recommendations is provided. Guidelines that are evidence-based may also contain consensus recommendations in areas where evidence is lacking, but these recommendations are clearly identified and appropriately graded.

Class V
Class V references may be the best information in the absence of other evidence. Expert opinion, panel consensus, literature reviews, and descriptive studies (case reports or case series) are subject to significant bias. A case series with comparison to historical controls can be plagued with missing data, and data extraction inconsistencies are common. The use of historical controls does not address how the diagnosis of disease or its treatment has evolved over time with newer technologies or medication. Text book information may be out of date by the time the book is published.

Comparative Effectiveness Research (CER)

Citations are designated with the CER label as part of the evidence classification if the article cited is one of the following:

1. A clinical trial or other clinical study that directly compares two or more health care interventions for the same clinical scenario.
2. A systematic review that compares two or more health care interventions by synthesizing the research from previous clinical studies.


American College of Radiology, ACR Appropriateness Criteria: radiologic management of lower-extremity venous insufficiency 2012. (IV)


Authors/Task Force et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). Eur J Vasc Endovasc Surg 2017. (IV)


Bosiers et al. Midterm results of the transarterial use of Onyx in the treatment of persisting type II endoleaks after EVAR. J Cardiovasc Surg (Torino) 2013. 54(4):469-75. (III)


Criado and Gashti. Are there patients truly at high-risk for carotid endarterectomy or carotid stenting? Can they be identified? Semin Vasc Surg 2008. 21(3):139-42. (V)


Fragkouli et al. Unusual death due to a bleeding from a varicose vein: a case report. BMC Res Notes 2012. 5:488. (V)


Gerhard-Herman et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American


Mazzolai et al. Diagnosis and management of acute deep vein thrombosis: a joint consensus document from the European society of cardiology working groups of aorta and peripheral circulation and pulmonary circulation and right ventricular function. Eur Heart J 2017. (IV)


Phan et al. Recent advances in the management of transient ischaemic attack: a clinical review. Intern Med J 2013. 43(4):353-60. (V)


Bibliography


Rantner et al. The risk of carotid artery stenting compared with carotid endarterectomy is greatest in patients treated within 7 days of symptoms. J Vasc Surg 2013. 57(3):619-26 e2; discussion 25-6. (I)


Rooke et al. 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline). Vascular medicine 2011. 16(6):452-76. (IV)


Touze et al. A clinical rule (sex, contralateral occlusion, age, and restenosis) to select patients for stenting versus carotid endarterectomy: systematic review of observational studies with validation in randomized trials. Stroke 2013. 44(12):3394-400. (I)


