The evidence supporting treatment of reflux and obstruction in chronic venous disease

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ABSTRACT

On July 20, 2016, a Medicare Evidence Development and Coverage Advisory Committee panel convened to assess the evidence supporting treatment of chronic venous disease. Several societies addressed the questions posed to the panel. A multidisciplinary coalition, representing nine societies of venous specialists, reviewed the literature and presented a consensus opinion regarding the panel questions. The purpose of this paper is to present our coalition's consensus review of the literature and recommendations for chronic venous disease. (J Vasc Surg: Venous and Lym Dis 2017;5:399-412.)

Lower extremity chronic venous disease (CVD) is most often caused by primary superficial venous reflux. It can also be caused by primary deep vein reflux or be the result of residual deep vein obstruction, with or without secondary deep vein reflux, after a prior episode of deep venous thrombosis (DVT). In many cases, a combination of these causes exists in a given limb.[1,2] Regardless of its origin, long-standing reflux or obstruction leads to chronic venous hypertension, which can cause symptoms and also trigger chronic inflammation in the skin, soft tissues, and veins of the lower leg, resulting in injury to these structures.[3,4] The spectrum of morphologic and functional venous abnormalities of the lower extremity that characterize CVD can be classified using the Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) scale.[5] The clinical component is most frequently used and classifies disease from C0 to C6, with higher C classifications corresponding to more severe CVD (Table I).

Several large epidemiologic studies have defined CVD as among the most prevalent ailments afflicting adults worldwide, more common than coronary, carotid, or peripheral arterial disease.[1,2,6-11] Fig 1 demonstrates the prevalence of venous disease using the CEAP scale identified in large cross-sectional studies of German,[11] Polish,[10] and American[2] populations. Epidemiologic studies have also demonstrated that CVD prevalence and severity increase with age. Fig 2 presents data from the Bonn Vein Study demonstrating the prevalence of venous disease stratified by the CEAP scale in patients 20 to 29, 50 to 59, and 70 to 79 years of age.[11]

CVD is a term used to describe the full spectrum of venous disease, regardless of whether it is the result of venous reflux, obstruction, or both. The post-thrombotic syndrome (PTS) is a chronic complication of DVT. It is the result of severe long-standing venous hypertension caused by incompletely recanalized vein segments or damaged valves resulting in venous reflux. The incidence of acute DVT in the United States is about 1 million per year. PTS develops in up to 40% of DVT patients within 2 years, and severe PTS (defined as severe quality of life [QOL]-affecting CVD) occurs in up to 11% of patients in that same time frame, significantly adding to the economic burden of caring for patients after prior DVT.[12-16]

The manifestations of CVD incur a substantial socioeconomic price tag, largely related to the direct costs of venous leg ulcer (VLU) care, its most severe complication, and the indirect costs of reduced productive activity and QOL.[8,17] Active or healed VLUs (C5-C6) are seen in about 1% to 3% of the U.S. population.[18] More than 50% of VLUs require care for >1 year to heal primarily.[19] VLUs result in an estimated 2 million lost workdays each year and may result in early retirement in as many as 13% of affected workers.[20]

Before the current therapies for superficial reflux and deep vein obstruction became available, treatment was likely underused by affected patients in part because of their concerns about the complications and side effects of treatment. Consequently, many patients with symptomatic CVD went untreated, resulting in a significant reduction in QOL in the affected population.[21,22] During

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Table I. Summary of basic Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) classification

Clinical classification	Description
C0	No visible or palpable signs of venous disease
C1	Telangiectasia or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation and/or eczema
C4b	Lipodermatosclerosis and/or atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer

the last 15 years, minimally invasive endovascular ambulatory alternatives have been developed to treat superficial reflux and deep vein obstruction without general anesthesia. There is a growing body of evidence that demonstrates the quicker recovery associated with these procedures. Consequently, patients have more aggressively accessed these less invasive treatment options, which is part of the reason for the recent increased use of these newer venous procedures.[23]

MEDICARE EVIDENCE DEVELOPMENT AND COVERAGE ADVISORY COMMITTEE (MEDCAC)

In the United States, health care for patients ≥65 years is funded through the Centers for Medicare and Medicaid Services (CMS). Legislation renders CMS responsible for making medical necessity health care coverage determinations at a national and regional level. The responsibility for national coverage determinations lies with the Coverage and Analysis Group in the Center for Clinical Standards and Quality. The Coverage group periodically uses its MEDCAC to generate public discussion and to provide recommendations about the evidence in focused clinical areas.

The MEDCAC is composed of approximately 100 experts in clinical and administrative medicine, public health, and other health care-related specialties as well as a representative from industry. The CMS coverage group periodically convenes a MEDCAC panel to assess the medical evidence and to provide guidance in areas of change, novelty, and controversy. Approximately 15 members of the Committee are selected to form the panel. Based on evidence presented to them in an open meeting, the panel votes on the strength of evidence supporting various diagnostic and treatment options. The Coverage group uses this advice in their decision-making.

On July 20, 2016, a MEDCAC panel convened to assess the evidence for treatment of CVD in the Medicare population.[24] Questions posed to the panel by the CMS Coverage group are shown in Table II. The format of this session included several invited presentations as well as a review of the findings of an Agency for Healthcare Research and Quality (AHRQ) commissioned Technical Assessment (TA) of the evidence related to the diagnosis and treatment of CVD. In the case of the MEDCAC convened to understand the evidence supporting the care of patients with CVD, the AHRQ TA limited its literature search to that published after January 1, 2000, excluding most of the foundational studies in the diagnosis and treatment of CVD. The AHRQ TA manuscript that resulted from this analysis is currently in a late-production phase for publication.

After these invited talks, representatives of several professional medical societies presented reviews of the

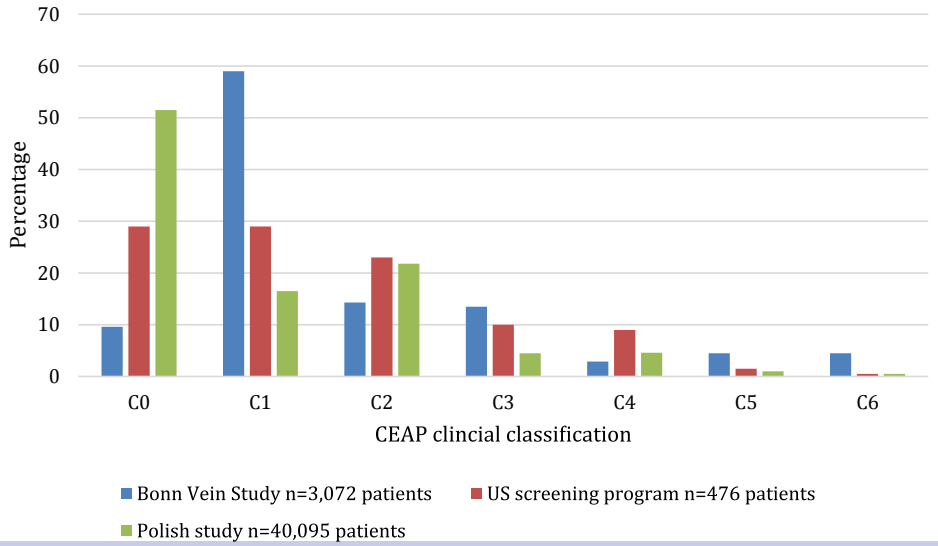

Fig 1. Distribution of chronic venous disease (CVD) by Clinical, Etiologic, Anatomic, and Pathophysiologic (*CEAP*) classification in three epidemiologic studies.