

# Cochrane for Clinicians

## Putting Evidence into Practice

### Deep Venous Thrombosis: Home vs. Inpatient Treatment

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### Clinical Question

Is home therapy for deep venous thrombosis (DVT) superior to in-hospital treatment in reducing recurrent venous thromboembolism (VTE)?

### Evidence-Based Answer

Patients treated at home with low-molecular-weight heparin (LMWH) have lower rates of recurrent VTE than those treated in a hospital (number needed to treat [NNT] = 23; 95% confidence interval [CI], 22 to 96). There were no clear differences in the occurrence of minor or major bleeding or death. Individual studies showed some improvement in quality-of-life measures with home therapy. Costs were lower for home treatment of VTE, with a savings of 3% to 64% over three to six months of therapy.<sup>1</sup> (Strength of Recommendation: B, based on inconsistent or limited-quality patient-oriented evidence.)

### Practice Pointers

DVT affects up to 900,000 U.S. adults (one to two per 1,000) annually. VTE refers to both DVT and pulmonary embolism (PE), and is estimated to cause 60,000 to 100,000 deaths in the United States per year.<sup>2</sup> Although historically VTE was initially managed in the inpatient setting with unfractionated heparin and warfarin, immediate

home management with LMWH and/or oral anti-coagulants has recently become a more common practice. The authors of this review compared the rate of recurrence, bleeding, and death in patients treated with inpatient protocols vs. exclusively outpatient protocols, while also examining the costs associated with treatment in the two settings.

This Cochrane review included seven trials with 1,839 patients from countries outside the United States.<sup>1</sup> The primary outcomes were recurrence of VTE, venous gangrene, minor or major bleeding, or death over three to 12 months of follow-up. Secondary outcomes included patient satisfaction, quality of life, and cost. Only a portion (between 23% and 49%) of patients in the included studies randomized to home VTE therapy were treated exclusively at home. Treatment of VTE (six trials; n = 1,708) at home resulted in lower rates of recurrence compared with inpatient treatment (NNT = 23; 95% CI, 22 to 96).

No differences were noted in the rates of minor or major bleeding or death. Quality of life was addressed in three studies, but the results were inconsistent; one study found no difference in quality of life between those treated at home or as inpatients, a second found an improved quality of life for those treated at home that did not persist to the 12th week of follow-up, and the third found only a small improvement in social function in those treated at home. Four studies reported on cost-effectiveness, and although the results of these could not be pooled, they demonstrated that inpatient VTE care cost more than home therapy. Home care savings over inpatient therapy varied from 3% to 64% in the studies, largely because of savings associated with direct hospitalization costs.

The authors rated the overall evidence as low to very low quality. Many patients in the home treatment group were initially hospitalized, and protocols to blind reviewers and randomize treatment allocation were not accomplished or not described in most of these studies. There was significant variation in exclusion criteria, such as whether PE was suspected or whether patients had received prior treatment for a thromboembolic event, which limits the applicability of this review's findings to the general population.<sup>3,4</sup> Further, the studies included in this review were

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conducted outside the United States, limiting generalizability to the domestic population.

Current American College of Chest Physicians guidelines on VTE treatment recommend home therapy for acute lower-extremity DVT and low-risk PE (i.e., clinically stable with good cardiopulmonary reserve) in appropriately selected patients. This includes those who feel well enough to be treated at home and who have well-maintained living conditions, strong support from family or friends, telephone access, and the ability to return to the hospital if deterioration occurs.<sup>5</sup>

The practice recommendations in this activity are available at <http://www.cochrane.org/CD003076>.

**Editor's Note:** Dr. Saguil is a Contributing Editor for *AFP*. In addition, the number needed to treat and confidence intervals reported in this Cochrane for Clinicians were calculated by the authors based on raw data provided in the original Cochrane review.

The views expressed in this article are the authors' and do not reflect the official policy or position of the Uniformed Services University of the Health Sciences, the Department of Defense, or the U.S. government.

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## Preventing or Delaying Type 2 Diabetes Mellitus with Diet and Exercise

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### Clinical Question

Can improved diet, increased physical activity, or both prevent or delay the development of type 2 diabetes mellitus in high-risk patients?

### Evidence-Based Answer

There is moderate-quality evidence that in patients with impaired glucose tolerance (IGT) defined by an abnormal 75-g two-hour glucose tolerance test, implementing changes in diet and adding physical activity together can prevent or delay the development of type 2 diabetes (absolute risk reduction [ARR] = 11%; 95% confidence interval [CI], 9.3% to 12.8%; number needed to treat = 9; 95% CI, 8 to 11). This review found no evidence that either diet or physical activity alone affects the incidence of type 2 diabetes in high-risk patients. Most of the included studies used IGT to define persons at high risk of diabetes; evidence is lacking about the effectiveness of diet and exercise in patients with prediabetes defined by other criteria, including elevated fasting blood glucose or elevated A1C levels.<sup>1</sup> (Strength of Recommendation: B, based on inconsistent or limited-quality patient-oriented evidence.)

### Practice Pointers

Prediabetes is commonly used to describe persons with intermediate hyperglycemia defined by impaired fasting glucose (IFG), IGT, or elevated A1C values lower than those that are diagnostic for diabetes. Persons with prediabetes have a higher risk of developing diabetes than those with normal blood glucose levels. The annual incidence of new diabetes in this population depends on the test used. In a given year, 4% to 6% of those with IGT will develop diabetes. Similarly, 6% to 9% of those with IFG, and 15% to 19% of those with both IGT and IFG will progress to diabetes.<sup>2</sup> There is a continuous association between an increasing A1C level and diabetes incidence; the five-year risk for patients with an A1C level between 5.5% and 6.0% is 9% to 25%, whereas the five-year risk for those with an A1C level greater than 6.0% to 6.5% is 25% to 50%.<sup>3</sup> Persons who have prediabetes are encouraged to modify their diet and increase physical activity to prevent progression to type 2 diabetes.<sup>4</sup> However, it is unclear if those interventions are effective.

This Cochrane review included 12 randomized controlled trials comprising 5,238 individuals with prediabetes. The trials compared diet, physical activity, or both with standard treatment or no treatment.<sup>1</sup> Standard treatment included recommendations, advice, or education about how to increase physical activity and reduce calories. The interventions were varied and included structured classes or individual instruction and support to increase activity and decrease calories for modest weight loss. The included trials followed patients for two to six years (mean duration = 3.6 years). Eleven studies used diet plus exercise vs. standard treatment or no treatment, one study compared a diet-only intervention with a physical-activity-only intervention or to standard treatment, and two compared physical activity only to standard treatment. Nine of the trials used IGT to

## SUMMARY TABLE: DIET PLUS EXERCISE VS. STANDARD TREATMENT TO PREVENT OR DELAY TYPE 2 DIABETES MELLITUS

Outcomes at 6 to 24 months (except as noted)	Probable outcome with a combined intervention of diet and exercise	Probable outcome with standard treatment	NNT or NNH (95% CI)	Number of participants (number of studies)	Quality of evidence
Incidence of type 2 diabetes (up to 6 years of follow-up; mean study duration = 3.8 years)	146 per 1,000	257 per 1,000	10 (8 to 11)	4,511 (11)	Moderate
Cardiovascular mortality (up to 6 years of follow-up; mean study duration = 3.1 years)	2 per 1,000	2 per 1,000	—	3,263 (7)	Very low
All-cause mortality (up to 6 years of follow-up; mean study duration = 3.6 years)	5 per 1,000	5 per 1,000	—	4,099 (10)	Very low
Mean direct medical costs (up to 3 years of follow-up)	\$225 to \$3,625	\$61 to \$184	—	2,775 (4)	Low
Serious adverse events	Not adequately reported	Not adequately reported	—	—	—

CI = confidence interval; NNH = number needed to harm; NNT = number needed to treat.

define prediabetes, and three used IFG instead of or in addition to IGT to define the population. None of the studies used A1C levels.

Participants included men and women 45 to 63 years of age from Asia, Scandinavia, the United Kingdom, and the United States. Studies were excluded if they compared diet or physical activity interventions with a pharmacologic intervention, or if the diet component consisted of a single food or supplement change.

In addition to the incidence of type 2 diabetes, the primary outcomes studied were all-cause mortality and serious adverse events. Studies that reported all-cause or cardiovascular mortality found no clinical or statistical differences, albeit with very-low-quality evidence. No serious adverse events were noted in the standard treatment or intervention groups, and patient-oriented outcomes such as blindness, renal failure, and quality of life were not reported.

This review lacks specific data about what constituted the changes in diet and physical activity. The National Institute of Diabetes and Digestive and Kidney Diseases recommends 5% to 10% weight loss through portion control and the “plate method,” and 150 combined minutes of moderate aerobic exercise and two sessions of resistance training per week.<sup>5</sup>

The practice recommendations in this activity are available at <http://www.cochrane.org/CD003054>.

**Editor’s Note:** The numbers needed to treat reported in this Cochrane for Clinicians were calculated by the author based on raw data provided in the original Cochrane review.

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