should be the first-line agents for treating stable angina. The authors note that these results may not be generalizable to patients with recent myocardial infarction, congestive heart failure, and diabetes mellitus, as subjects with those comorbidities were excluded from these trials. However, BBs have been shown to improve outcomes for patients in each of these groups[1-3] and should be the first-line agents for these patients as well. Nifedipine is poorly tolerated and should be avoided. LANs may be associated with an increase in as-needed nitroglycerin use and should be second-line agents.

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Low-Molecular-Weight Heparin for Deep Venous Thrombosis

Gould MK, Dembitzer AD, Doyle RL, Hastie TJ, Garber AM. Low-molecular-weight heparins compared with unfractionated heparin for treatment of acute deep venous thrombosis: a meta-analysis of randomized, controlled trials. Ann Intern Med 1999; 130:800-9.

Clinical question **Is therapy with low-molecular-weight heparin (LMWH) as safe and effective as conventional unfractionated heparin (UFH) for the treatment of deep venous thrombosis (DVT)?**

Background Conventional treatment of acute DVT requires hospitalization and use of UFH. Treatment with LMWH is simpler and more convenient. This medication may be self-administered either once or twice daily and does not require close monitoring with laboratory tests or dosage adjustment. A key clinical issue is whether this form of therapy is as safe and effective as treatment with standard UFH. This study used the most recent data available to estimate the likelihood of clinically important patient-oriented outcomes.

Population studied The authors performed a meta-analysis of 11 studies with a total of 3674 patients with acute lower extremity DVT, with or without coexisting pulmonary embolism. The population included patients with distal DVT, previous venous thromboembolism, cancer, heart failure, prolonged bed rest, and recent surgery or trauma. All were followed up for at least 3 months.

Study design and validity The authors attempted to identify all studies published between 1985 and 1997 using the MEDLINE database. They also reviewed the reference lists of identified studies and contacted the investigators and pharmaceutical companies to locate unpublished studies. The authors used previously published study quality criteria,[1] including assessment of proper randomization, proper concealment of randomization, double-blinding, and the number of patients lost to follow-up. Included were only studies that enrolled patients with an acute lower extremity DVT, randomly assigned treatment groups, compared a fixed dose of LMWH with an adjusted dose of UFH, used objective methods to confirm DVT, and used objective methods to assess the clinical outcomes. One limitation of this study is that the authors pooled the results for different agents. The 2 agents available in the United States, enoxaparin (Lovenox) and dalteparin (Fragmin), were studied in 634 and 705 patients, respectively.

Outcomes measured Three patient-oriented outcomes were measured: major bleeding complications during the initial treatment period, recurrent thromboembolic events during 3 to 6 months, and mortality rates during 3 to 6 months after initiation of therapy. Data were also extracted for minor bleeding episodes, thrombocytopenia, the death rate from recurrent thromboembolism, and the death rate among participants with cancer.

Results Of 966 potentially relevant studies, only 11 met the inclusion criteria. The risk of a major bleeding episode favored LMWH (odds ratio [OR] = 0.57; 95% confidence interval [CI], 0.33 - 0.99), but the absolute risk reduction (ARR) was small and not statistically significant (ARR = 0.61%; 95% CI, 0.04% - 1.26%). Recurrent thromboembolic events were slightly less common in patients treated with LMWH, but again the difference was not statistically significant (OR = 0.85; 95% CI, 0.63 - 1.14). LMWH did significantly reduce the mortality rate over 3 to 6 months (OR = 0.71; 95% CI, 0.53 - 0.94; ARR = 1.65%; number needed to treat = 61). It has been observed that LMWH reduces mortality rates in patients with cancer, but this benefit alone could not explain the statistically significant reduction in mortality for all patients. The authors did not find statistically significant benefits of LMWH for minor bleeding episodes or for thrombocytopenia. A detailed sensitivity analysis generally confirmed the robustness of the results. More than 5 trials with negative results would have to be published in the future and included in a future meta-analysis to overcome the mortality advan-

tage of LMWH demonstrated in this study.

Recommendations for clinical practice **LMWH significantly reduces mortality rates after acute DVT. They are also as safe and effective as UFH with regard to major bleeding episodes and preventing recurrence of DVT. Perhaps most important, using LMWH is easier and more convenient, allowing for early hospital discharge or outpatient treatment. This well-done meta-analysis supports similar findings in earlier studies. An article that accompanies this one in the same issue of *Annals of Internal Medicine*[2] adds to the mounting evidence that LMWH is a more cost-effective treatment option as well. The best available evidence regarding treatment of acute DVT in terms of efficacy, safety, cost, and convenience suggests that LMWH should replace UFH.**

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Urethral Barriers for Stress Incontinence

Brubaker L, Harris T, Gleason D, Newman D, North B, and the Miniguard Investigators Group. The external urethral barrier for stress incontinence: a multicenter trial of safety and efficacy. Obstet Gynecol 1999; 93:932-7.

Clinical question **Is the use of an external urethral barrier a safe and effective treatment for stress urinary incontinence in women?**

Background Stress urinary incontinence is the most common type of incontinence in women and has a very significant impact on their daily lives. This manufacturer-supported study was designed to evaluate the safety and efficacy of the Miniguard external urethral barrier.

Population studied A total of 411 women with self-reported symptoms of mild to moderate stress urinary incontinence were enrolled from 12 centers in the United States. Women were excluded for the following reasons: symptoms of urinary tract infection, vaginitis, or intralabial irritation; skin sensitized by soaps, lotions, or feminine products; a urethral meatus inside the vaginal opening; a postvoid residual urine >200 cc; pelvic surgery within the last 5 months; inability to understand instructions for use; or inability to properly place barrier. Women ranged in age from 18 to 78 years (average age = 49 years). Approximately 25% of the study population were postmenopausal, and more than half of them were taking estrogen preparations.

Study design and validity This was an uncontrolled trial designed to evaluate the safety and efficacy of this particular device. Of the 411 women who entered the study, 390 began device use and 346 completed the study. The authors verified the dropout reasons for each of the 65 women who did not complete the study.

The study period was 21 weeks, consisting of a 1-week qualifying period, a 4-week baseline assessment, 12 weeks of device use, and 4 weeks of follow-up. Patients received an instruction sheet and a toll-free number for assistance and were required to be able to place the device properly within 3 attempts. They were also given a daily journal, a 7-day voiding journal, and materials for a home pad test (12 waking hours) to be completed before the second visit. They were given devices every 4 weeks and instructed to use the device as their normal incontinence protection. Efficacy was evaluated through the use of questionnaires, voiding diaries, and pad testing. Safety was evaluated through monitoring for urinary tract infection, vulvar irritation, vaginitis, urinary retention, and detrusor overactivity. There was no comparison made between this barrier method and any other nonsurgical treatment method for urinary incontinence. Major weaknesses of the study include its convenience sample, lack of a comparison group, manufacturer support, and lack of blinding of raters for evaluation of data.

Outcomes measured The primary patient-oriented outcomes for this study were a reduction in the number of leakage episodes recorded in a 7-day voiding diary, subjective leakage severity scores, incontinence impact scores, and pad-test loss during device use. Safety outcomes included lack of statistically and clinically significant change in the percentage of patients with a urinary tract infection during device use or in the postvoid residual urine volume.

Results The study participants used an average of 4 devices per day for approximately 9 hours per day. Most participants reported that the device was comfortable (89% by week 9, 93% by week 17). Women reported a significant decrease in the urinary leakage severity score while wearing the device from a baseline average score of 10 to an average score of 3 by week 9. When the device was discontinued for 4 weeks, the average score increased to 7. The incontinence impact questionnaire results revealed a positive impact on the quality of life. There was no statistically significant change in the percentage of women with positive urine cultures during