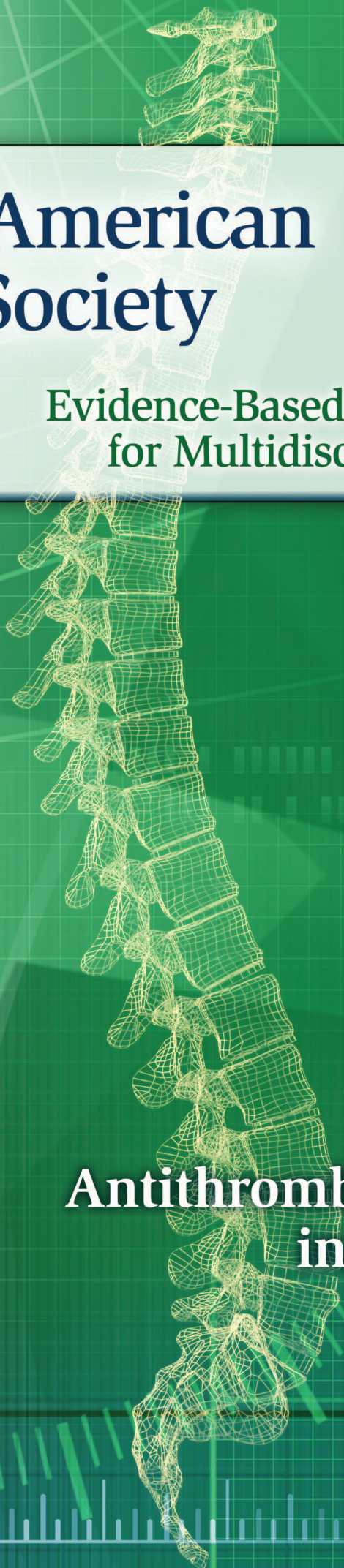
North American Spine Society

Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care



Antithrombotic Therapies in Spine Surgery

North American Spine Society

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for Multidisciplinary Spine Care

Antithrombotic Therapies in Spine Surgery

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Financial Statement

This clinical guideline was developed and funded in its entirety by the North American Spine Society (NASS). All participating authors have submitted a disclosure form relative to potential conflicts of interest which is kept on file at NASS.

Comments

Comments regarding the guideline may be submitted to the North American Spine Society and will be considered in development of future revisions of the work.

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Table of Contents

This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

I. Introduction

Objective

The objective of the North American Spine Society (NASS) Evidence-Based Clinical Guideline on Antithrombotic Therapies in Spine Surgery is to provide evidence-based recommendations to address key clinical questions surrounding the use of antithrombotic therapies in spine surgery. The guideline is intended to address these questions based on the highest quality clinical literature available on this subject as of February 2008. The goals of the guideline recommendations are to assist in delivering optimum, efficacious treatment with the goal of preventing thromboembolic events.

Scope, Purpose and Intended User

This document was developed by the North American Spine Society Evidence-based Guideline Development Committee as an educational tool to assist spine surgeons in minimizing the risk of deep venous thrombosis (DVT) and pulmonary embolism (PE). The NASS Clinical Guideline on Antithrombotic Therapies in Spine Surgery discusses the incidence of DVT/PE in the population of patients undergoing spinal surgery. Recommendations are made to address the utilization of chemoprophylaxis and mechanical prophylaxis, with discussion of wound complications and risks associated with prophylactic measures.

THIS GUIDELINE DOES NOT REPRESENT A "STANDARD OF CARE," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more extensive prophylaxis than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and doctor's professional judgment. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.

Patient Population

The patient population for this guideline encompasses adults (18 years or older) undergoing spine surgery.

II. Guideline Development Methodology

Through objective evaluation of the evidence and transparency in the process of making recommendations, it is NASS' goal to develop evidence-based clinical practice guidelines for the diagnosis and treatment of adult patients with various spinal conditions. These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes. It is anticipated that where evidence is very strong in support of recommendations, these recommendations will be operationalized into performance measures.

Multidisciplinary Collaboration

With the goal of ensuring the best possible care for adult patients suffering with back pain, NASS is committed to multidisciplinary involvement in the process of guideline and performance measure development. To this end, NASS has ensured that representatives from medical, interventional and surgical spine specialties have participated in the development and review of all NASS guidelines. It is also important that primary care providers and musculoskeletal specialists who care for patients with spinal complaints are represented in the development and review of guidelines that address treatment by first contact physicians, and NASS has involved these providers in the development process as well. To ensure broad-based representation, NASS has invited and welcomes input from other societies and specialties.

Evidence Analysis Training of All NASS Guideline Developers

NASS has initiated, in conjunction with the University of Alberta's Centre for Health Evidence, an online training program geared toward educating guideline developers about evidence analysis and guideline development. All participants in guideline development for NASS have completed the training prior to participating in the guideline development program at NASS. This training includes a series of readings and exercises, or interactivities, to prepare guideline developers for systematically evaluating literature and developing evidence-based guidelines. The online course takes approximately 15-30 hours to complete and participants are awarded CME credit upon completion of the course.

Disclosure of Potential Conflicts of Interest

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues and their potential conflicts have been documented for future reference. They will not be published in any guideline, but kept on file for reference, if needed. Participants have been asked to update their disclosures regularly throughout the guideline development process.

Levels of Evidence and Grades of Recommendation

NASS has adopted standardized levels of evidence (Appendix B) and grades of recommendation (Appendix C) to assist practitioners in easily understanding the strength of the evidence and recommendations within the guidelines. The levels of evidence range from Level I (high quality randomized controlled trial) to Level V (expert consensus). Grades of recommendation indicate the strength of the recommendations made in the guideline based on the quality of the literature.

Grades of Recommendation:

A: Good evidence (Level I studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

The criteria for assigning these levels of evidence and grades of recommendation are the same as those used by the Journal of Bone and Joint Surgery, the American Academy of Orthopaedic Surgeons, Clinical Orthopaedics and Related Research, the journal Spine and the Pediatric Orthopaedic Society of North America.

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a potential level of evidence. As an example, a therapeutic study designed as a randomized controlled trial would be considered a potential Level I study. The study would then be further analyzed as to how well the study design was implemented and significant short comings in the execution of the study would be used to downgrade the levels of evidence for the study's conclusions. In the example cited previously, reasons to downgrade the results of a potential Level I randomized controlled trial to a Level II study would include, among other possibilities, an underpowered study (patient sample too small, variance too high), inadequate randomization or masking of the group assignments and lack of validated outcome measures.

In addition, a number of studies were reviewed several times in answering different questions within this guideline. How a given question was asked might influence how a study was evaluated and interpreted as to its level of evidence in answering that particular question. For example, a randomized control trial reviewed to evaluate the differences between the outcomes of patients who received antibiotic prophylaxis with those who did not might be a well designed and implemented Level I therapeutic study. This same study, however, might be classified as giving Level II prognostic evidence if the data for the untreated controls were extracted and evaluated prognostically.

Guideline Development Process

■ Step 1: Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The lists were compiled into a master list, which was then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, served to focus the guideline.

■ Step 2: Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because NASS is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross section of NASS membership is represented on each group whenever feasible. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

■ Step 3: Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (Appendix D) which has been followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members have iden-

tified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the appendices (Appendix E).

- **Step 4: Completion of the Literature Search**

After each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history in EndNote,™ for future use or reference.

- **Step 5: Review of Search Results/ Identification of Literature to Review**

Work group members reviewed all abstracts yielded from the literature search and identified the literature they would review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members identified the best research evidence available to answer the targeted clinical questions. That is, if Level I, II and/or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

- **Step 6: Evidence Analysis**

Members of the work group independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members reviewed each article selected and independently assigned levels of evidence to the literature using the NASS levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. The consensus level (the level upon which two thirds of reviewers were in agreement) was then assigned to the article.

As a final step in the evidence analysis process, members identified and documented gaps in the evidence to educate guideline readers about where evidence is lacking and help guide further needed research by NASS and other societies.

- **Step 7: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus**

Work groups held Web casts to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate"). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, work group members developed the guideline content, addressing the literature which supports the recommendations.

■ Step 8: Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence-based Guideline Development Committee, the Research Council Director and the Advisory Panel for review and comment. The Advisory Panel is comprised of representatives from physical medicine and rehab, pain medicine/management, orthopedic surgery, neurosurgery, anesthesiology, rheumatology, psychology/psychiatry and family practice. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

■ Step 9: Submission for Board Approval

After any evidence-based revisions were incorporated, the drafts were prepared for NASS Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

■ Step 10: Submission for Endorsement, Publication and National Guideline Clearinghouse (NGC) Inclusion

Following NASS Board approval, the guidelines were slated for publication, submitted for endorsement to all appropriate societies and submitted for inclusion in the National Guidelines Clearinghouse (NGC). No revisions were made at this point in the process, but comments have been and will be saved for the next iteration.

■ Step 11: Identification and Development of Performance Measures

The recommendations will be reviewed by a group experienced in performance measure development (eg, the AMA Physician's Consortium for Performance Improvement) to identify those recommendations rigorous enough for measure development. All relevant medical specialties involved in the guideline development and at the Consortium will be invited to collaborate in the development of evidence-based performance measures related to spine care.

■ Step 12: Review and Revision Process

The guideline recommendations will be reviewed every three years by an EBM-trained multidisciplinary team and revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the guideline.

III. Incidence of DVT/PE in Spine Surgery

The body of scientific and clinical literature on the topic of deep vein thrombosis (DVT) and pulmonary embolism (PE) is extensive. Either can occur spontaneously or after a risk-enhancing event such as an injury or a surgical procedure. A variety of factors, including the patient's health and genetic background, can influence the risk of this life threatening complication.

Managing this risk in patients undergoing spinal surgery can pose substantial challenges. Treatment of DVT or a PE using anticoagulants in the immediate postoperative period may potentially lead to catastrophic neurologic decline from epidural bleeding at the surgical site.

A. Incidence of DVT/PE in Unprophylaxed Patients

In order to appreciate the incidence of these thrombosis-related complications in patients undergoing spinal surgery without antithrombotic prophylaxis, the work group performed a comprehensive literature search and analysis. The group reviewed 45 articles that were selected from a search of MEDLINE (PubMed), Cochrane Register of Controlled Trials, Web of Science and EMBASE Drugs & Pharmacology that addressed the incidence and natural history of DVT and PE associated with spinal surgery.

Analysis of the questions related to the natural history of DVT in spinal surgery patients not receiving any prophylactic therapies was difficult due to a number of issues.

1. Very few studies have been done in recent years in which absolutely no prophylaxis was used. Mechanical pumps and/or compressive stockings are widely and routinely used after spinal surgery so that studies without such are rare.
2. The diagnostic method for DVT and PE vary widely between publications. Older studies report only clinically evident thrombotic events. More recent studies, in large part due to evolving technology, rely on a variety of different diagnostic methods including radionuclide scans, venograms or ultrasound-based imaging. Thus, comparison of outcomes between different studies that use distinctly different diagnostic criteria is of questionable validity.
3. The patient populations addressed in the world literature vary widely. The study groups varied in age, ethnicity (potentially influencing genetic susceptibility), magnitude and length of surgery, and postoperative mobilization, all of which might influence the risk for thromboembolic disease. For example, it is well-established that bed rest is a risk factor for DVT. However, the pace at which patients are mobilized after spinal surgery varies widely. Mobilization protocols are rarely reported in detail in spine surgical studies.

Because of these issues, the work group was unable to definitively answer the posed questions related to incidence of DVT/PE in spinal surgery patients not receiving prophylactic antithrombotic therapies. However, the work group felt that several important suggestions can be made based on the literature reviewed. These are included below along with a detailed analysis of the small subset of papers that met the guideline's inclusion criteria and provided information that was germane to the discussion of incidence in this patient population.

What is the overall rate (symptomatic and asymptomatic) of DVT or PE following elective spinal surgery without any form of prophylaxis?

What are the relative rates of clinically symptomatic DVT or PE (including fatal PE) without any form or prophylaxis following elective cervical, thoracic, and lumbar surgery?

Work Group Conclusions/Suggestions:

1. Deep vein thrombosis and subsequent pulmonary embolus can occur following spinal surgery, which in turn can lead to morbidity and death. Anyone participating in the care of spinal surgery patients should be aware of these conditions as known potential events.

2. The incidence of DVT and PE in patients undergoing spinal surgery likely varies according to the magnitude of the surgery and perioperative mobilization.

3. The use of "historical controls" to address the incidence of DVT or PE in a perioperative population is probably not appropriate.

4. Clinical examination alone is not a reliable method to confirm the diagnosis of a DVT. Objective diagnostic methods, such as venography or Doppler ultrasound, should be used to confirm a suspected DVT in postoperative spine patients. Future studies to characterize the incidence of DVT in postoperative spine patients should use objective diagnostic methods such as venography or Doppler ultrasound.

Gruber et al[18] performed a prospective comparative study to determine the incidence of bleeding complications in patients undergoing lumbar disc surgery treated with minidose heparin-dihydroergotamine (DHE) or placebo. Of the 50 patients included in the study, 25 received 2500IU heparin-DHE twice daily and 25 were assigned to the placebo group. Injections were administered two hours preoperatively, with postoperative administration at 12-hour intervals for at least seven days or until the patient was discharged from the hospital. Of the 25 assigned to the control group, five had received heparin at another hospital and were excluded from the analysis. Surgeons reported bleeding and, if clinically suspected, DVT was diagnosed by phlebogram, plethysmography, Doppler ultrasound or I125 fibrinogen test. If a PE was suspected, a chest radiograph, ECG, ventilation-perfusion scan or pulmonary angiogram was obtained. The authors reported no clinically evident DVT or PE events in this small series of consecutive patients. The authors noted increased intraoperative bleeding in 24% (6/25) of patients in the heparin-DHE group and 28% in the placebo group, a difference that was not statistically significant.

In critique of this study, diagnostic methods for DVT were not standardized and only conducted when prompted by clinical suspicion. Furthermore, patient numbers were quite low and the definition of "lumbar disc operations" was unclear. Due to these methodological limitations, this potential Level II study provides Level III evidence of a low risk of DVT/PE in patients undergoing lumbar disc surgery.

Joffe et al[20] reported results of a prospective case series investigating the incidence of DVT in patients undergoing elective neurosurgical procedures. Of the 23 neurosurgical patients included in the study, only 10 were spinal cases. All patients were screened daily for the duration of their hospital stay (which was at least seven days) for DVT with an I125 fibrinogen test and Doppler ultrasound. The authors reported that 60% of the spinal patients (6/10) developed asymptomatic postoperative DVT. They concluded that neurosurgical patients are at risk for DVT and that these patients

are often asymptomatic. Based on their findings, the authors further suggested that DVT will be underdiagnosed by clinical criteria alone.

In critique, this was a very small study consisting of only a few spinal patients without details about the type and extent of spine surgery. Due to these weaknesses, this potential Level IV study provides Level V evidence that asymptomatic DVT is not uncommon in a nonselect group of patients undergoing elective spinal surgery likely followed by prolonged periods of bed rest, an assumption made based on the year the study was published. The applicability of these findings today is questionable given that prolonged periods of bed rest are no longer recommended following surgery.

Lee et al[22] conducted a prospective comparative study to determine the rate of DVT following elective major reconstructive spinal surgery without antithrombotic therapies in an East Asian (Korean) population. All 313 patients included in the study were screened via duplex ultrasonography between the fifth and seventh postoperative days. Authors reported a 1.3% (4/313) overall incidence of DVT, with a clinically symptomatic presentation in only 0.3% (1/313) of patients. The authors concluded that East Asians undergoing these procedures do not get DVT often enough to warrant prophylaxis. The authors further suggested that routine screening and prophylaxis in this specific patient population is not warranted.

In critique of this study, an unknown number of pediatric patients were included. A subgroup analysis addressing the adult population was not provided. In addition, patients were treated with postoperative bed rest for a mean of 7.4 days. This potential Level I study provides Level II evidence suggesting a lower incidence of DVT after elective major reconstructive spinal surgery without antithrombotic therapy than previously reported. Although the authors concluded this incidence was related to the ethnicity of the patient group, it should be noted that other unidentified factors may have influenced the DVT rate.

Oda et al[30] reported a prospective comparative study documenting the prevalence of DVT after posterior spinal surgery in patients not receiving antithrombotic therapies. Of the 134 patients included in the study, 110 were screened for DVT by venography within 14 days of surgery (mean = 7.2 days) and clinically followed for at least three months. Authors reported that 15.5% (17/110) of patients had venographic evidence of DVT, while none had clinical manifestations of DVT. The authors also indicated the prevalence of DVT by surgical region; 26.5% of lumbar, 14.3% of thoracic and 5.6% of cervical patients had venographic evidence of DVT. Statistical comparison between patients who did and did not have DVT demonstrated that increased age was a statistically significant risk factor (Mann–Whitney test; $P< 0.05$). The authors concluded that the incidence of DVT after posterior spinal surgery is higher than generally appreciated. Therefore, they felt that further study is necessary to clarify the appropriate screening method for and prophylaxis of DVT after spinal surgery.

This study provides Level II evidence that the rate of DVT in postoperative spine surgery patients may be underestimated. Clinical manifestations are not reliable for the diagnosis of DVT. Increased age and posterior lumbar surgery are risk factors. It should also be noted that all patients included in this study had an interval of bed rest following surgery. The applicability of these findings today is questionable given that prolonged periods of bed rest are no longer recommended following surgery.

Uden et al[40] described a retrospective case series documenting the rate of clinically evident DVT in a population of 1229 patients treated surgically with Harrington instrumentation followed by three to five weeks of bed rest. Diagnosis of DVT was confirmed via contrast and/or isotope phlebography only when clinically suspected or by autopsy. The authors reported a 0.65% (8/1229) incidence of DVT and 0.08% (1/1229) incidence of PE in this scoliosis patient population.

In critique of this study, patients were not enrolled at the same point in their disease and some patients were

younger than 18 years. Some patients had two separate surgeries performed, though subgroup analyses were not provided. Diagnostic methods were variably applied to only those patients with clinical suspicion of DVT, with no standardized follow-up or duration identified. Because of these methodological weaknesses, this potential Level III study provides Level IV evidence that clinically evident DVT can occur in scoliosis patients managed with postoperative bed rest. Because this rate is based upon screening of only those patients with clinical suspicion of DVT, the incidence was likely underestimated in this patient population.

Future Directions for Research

The North American Spine Society believes that deliberately withholding antithrombotic therapies, thereby exposing patients to increased risks of DVT and PE, in order to more thoroughly investigate the rate of DVT/PE in an unprophylaxed patient population undergoing elective spine surgery is unethical. For practical purposes, the North American Spine Society is satisfied to base its recommendations for the use of antithrombotic therapies on the results of existing data, and does not call for a definitive natural history study to be conducted of patients receiving no mechanical prophylaxis.

What is the overall rate (symptomatic and asymptomatic) of DVT or PE in nonsurgically treated acute spine trauma or tumor patients without any form of prophylaxis?

What is the overall rate (symptomatic and asymptomatic) of DVT or PE following nonelective spinal surgery for spine trauma or malignancy without any form of prophylaxis?

What is the rate of clinically symptomatic DVT or PE (including fatal PE) following nonelective spinal surgery for spine trauma or malignancy without any form of prophylaxis?

A systematic review of the literature did not reveal any high-quality studies with appropriate subgroup analyses to address these specific questions.

Future Directions for Research

The North American Spine Society believes that deliberately withholding antithrombotic therapies, thereby exposing patients to increased risks of DVT and PE in order to more thoroughly investigate the rate of DVT/PE in an unprophylaxed patient population undergoing nonelective spine surgery is unethical. For practical purposes, the North American Spine Society is satisfied to base its recommendations for the use of antithrombotic therapies on the results of existing data, and does not call for a definitive natural history study to be conducted.

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B. Incidence of DVT/PE in Prophylaxed Patients

What is the rate of clinically symptomatic DVT and/or PE (including fatal PE) following elective spinal surgery with one or more of the following prophylaxis measures: compression stockings, mechanical sequential compression devices, chemoprophylaxis medication? (PROGNOSTIC QUESTION)

The few eligible studies reviewed by the work group provided limited information regarding the relative incidence of venous thromboembolism (VTE) complications for specific antithrombotic prophylactic measures within specific spine surgery patient subpopulations (eg, single-level corpectomy patients). Furthermore, there is not enough data to definitively state the rate of clinically symptomatic DVT and/or PE for each type of spinal surgical intervention and prophylactic measure. Given the inability to generalize reported incidences to the variety of surgeries with different prophylactic protocols, the work group was unable to address this question.

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IV. Recommendations for Appropriate Antithrombotic Therapies in Spine Surgery

A. Efficacy of Antithrombotic Therapies

Do prophylactic antithrombotic measures, including compression stockings, mechanical sequential compression devices and chemoprophylaxis medications, decrease the rate of clinically symptomatic DVT and/or PE (including fatal PE) following elective spinal surgery? (THERAPEUTIC QUESTION)

A comprehensive review of the literature suggests that most commonly-performed elective spine surgeries done through a posterior approach are associated with a very low risk of VTE. In this setting, chemoprophylaxis may not be warranted as it is accompanied by a definable risk of serious wound and bleeding complications. Postoperative chemoprophylaxis may be considered for long and complex surgeries, such as anterior or combined anterior-posterior approaches, and in patients with known thromboembolic risk factors, such as paralysis, spinal cord injury, malignancy, or hypercoagulable state. However, mechanical prophylaxis of any type, such as pneumatic sequential compression boots or compression stockings, should be considered following any in-patient spine surgery due to the documented efficacy and low complication rates of these devices.

RECOMMENDATION: Mechanical compression devices in the lower extremities are suggested in elective spinal surgery to decrease the incidence of thromboembolic complications.

GRADE OF RECOMMENDATION: B

Rokito et al[21] prospectively studied the incidence of DVT after elective major adult spinal surgery in order to identify the optimal mode of prophylaxis. Of the 329 patients included in the study, 110 patients were prospectively randomized to one of three study groups. Group 1 (42 patients) received bilateral thigh-high thrombosis embolic deterrent (TED) compression stockings. Group 2 (33 patients) received TED stockings and thigh-length cuffs that provided sequential pneumatic compression to the calf and thigh. Group 3 (35 patients) received TED stockings and low-dose Coumadin (warfarin). The 219 patients not randomized received either TED stockings alone or TED stockings and pneumatic compression boots for DVT prophylaxis. The authors reported that 0.3% (1/329) of patients were diagnosed with a DVT. Moreover, they also found that 5.7% of patients treated with Coumadin experienced bleeding complications.

Due to the unstated randomization process, this potential Level II case control study provides Level III therapeutic evidence that low-dose Coumadin is no more effective than mechanical prophylaxis in reducing DVT risks. Given the increased risk of hemorrhage with Coumadin, mechanical prophylaxis with graduated compression stockings and pneumatic compression boots is preferable to anticoagulation therapy.

Wood et al[27] reported results of an RCT conducted on patients undergoing elective anterior or posterior thoracic, thoracolumbar, or lumbar multilevel decompressions and/or spinal fusions. They compared two different types of prophylactic protocols (elastic

stockings/foot wraps versus elastic stockings/pneumatic compression boots) for the prevention of DVT/PE after complex spinal surgery. Of the 136 consecutively assigned patients, data were available on 134. Mechanical prophylaxis via elastic stockings and foot wraps was used for 75 patients, while 59 received elastic stockings and pneumatic compression boots. The authors reported a 1.5% (2/136) incidence of DVT and a 0.7% (1/136) incidence of PE and concluded that mechanical prophylaxis is effective in reducing DVT risk after major spinal surgery.

Due to the unclear randomization process utilized, this potential Level I study provides Level II therapeutic evidence that mechanical prophylaxis is effective in reducing DVT risk after major spine surgery. The findings suggest that one form of mechanical prophylaxis is not superior to the other.

RECOMMENDATION: TED stockings in combination with acetylsalicylic acid (ASA) are an option in elective spinal surgery to decrease the incidence of thromboembolic complications.

GRADE OF RECOMMENDATION: I (Insufficient Evidence)

Nelson et al[19] described a prospective randomized controlled trial evaluating the incidence of DVT following posterior lumbar decompression with instrumented fusion in patients using TED stockings and acetylsalicylic acid (ASA) compared with those using TED stockings, pneumatic compression boots and ASA during surgery. Of the 117 patients included in the study, 60 were randomly assigned to receive ASA 600mg bid and TED stockings and 57 were randomly assigned to receive ASA 600mg bid, TED stockings and pneumatic compression boots. The authors found that at two to six days postoperatively, no patients in either group were diagnosed via clinical exam and ultrasound with DVT, and concluded that the use of TED stockings in combination with ASA 600mg bid is sufficient for DVT prophylaxis in this patient population.

Due to unstated randomization techniques and the small sample size, this potential Level I study provides Level II therapeutic evidence supporting the use of TED stockings in combination with ASA 600mg bid to decrease the incidence of DVT. These results suggest that the addition of pneumatic compression boots does not provide any added protection against DVT.

RECOMMENDATION: Most commonly-performed elective spine surgeries done through a posterior approach are associated with a very low risk of VTE. In this setting, chemoprophylaxis may not be warranted as it is accompanied by a definable risk of serious wound and bleeding complications. Low molecular weight heparin (LMWH) or low-dose warfarin may be used postoperatively to lower the risk of thromboembolic complications following elective combined anterior-posterior (circumferential) spine surgery or in patients identified as having a high risk for thromboembolic disease, such as multiple trauma, malignancy or hypercoagulable state. These therapies should be considered carefully and on an individual case-by-case basis, as use may place patients at increased risk of bleeding complications.

GRADE OF RECOMMENDATION: Work Group Consensus Statement

Future Directions for Research

Recommendation #1: A randomized controlled trial comparing mechanical prophylaxis alone (i.e. pneumatic compression boots or compression stockings) with combined LMWH and mechanical prophylaxis in high-risk patients can be performed to assess the respective incidence of DVT, PE, neurological deterioration secondary to epidural hematoma, postoperative bleeding, and wound complications.

Recommendation #2: A randomized controlled trial

comparing mechanical prophylaxis alone (i.e. pneumatic compression boots or compression stockings) with combined low-dose warfarin and mechanical prophylaxis in high-risk patients can be performed to assess the respective incidence of DVT, PE, neurological deterioration secondary to epidural hematoma, postoperative bleeding, and wound complications.

Recommendation #3: A prospective, uncontrolled, prognostic multicenter study of a high number of patients undergoing a wide variety of spine surgeries can be undertaken to quantify the relative risk of a number of suspected predisposing factors for VTE that would include, but not be limited to, length of surgery, number of levels fused, underlying diagnosis, traumatic injury, paralysis and SCI. In addition, the relative risks of postoperative neurological deterioration from epidural hematoma, bleeding, wound complications, and transfusion requirements should be scrupulously defined for each subgroup.

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B. Mechanical Prophylaxis

When indicated, what is the ideal time to begin mechanical prophylaxis in relation to spinal surgery?

When indicated, how long should mechanical prophylaxis continue following spinal surgery?

RECOMMENDATION: Although evidence in the spine literature is limited regarding timing and duration of mechanical prophylaxis, initiation of mechanical compression just prior to or at the beginning of surgery and continuation until the patient is fully ambulatory is a reasonable practice. While several studies cited start and stop times consistent with this recommendation, no studies specifically assessed this issue in a comparative fashion.

GRADE OF RECOMMENDATION:
Work Group Consensus Statement

Future Directions for Research

After careful consideration of this literature, the work group determined that a future prospective comparative study would be highly impractical as it would be invariably underpowered due to the large number of patients required to demonstrate a statistically significant difference.

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C. Chemoprophylaxis

RECOMMENDATION: The utility and safety of chemoprophylaxis following spinal surgery is controversial. Because of the hazardous risk of symptomatic epidural hematoma, the potential consequences may confound the benefits of these agents. Unfortunately, scientific scrutiny of chemoprophylaxis in elective spinal surgery has been limited to case series involving discectomy and decompression. Evidence is better established in higher risk patients undergoing spinal surgery for traumatic or neoplastic conditions, although safety and efficacy have not been thoroughly studied in these conditions either. Most commonly-performed elective spine surgeries done through a posterior approach are associated with a very low risk ofVTE. In this setting, chemoprophylaxis may not be warranted as it is accompanied by a definable risk of serious wound and bleeding complications. When chemoprophylaxis is utilized, neurological status should be closely monitored.

GRADE OF RECOMMENDATION: Work Group Consensus Statement

When indicated, what is the ideal time to begin chemoprophylaxis in relation to spinal surgery?

RECOMMENDATION: Although the literature does not support an ideal time to begin chemoprophylaxis, initiating low molecular weight heparin (LMWH) preoperatively can decrease the incidence of thromboembolic disease. However, this is associated with an increased risk of bleeding complications. There is Level IV evidence that LMWH can be started safely the day of elective spine surgery. 4,9,10,22,25 It is the work group's recommendation that LMWH be used cautiously prior to routine, elective spinal surgery, and withheld unless there are other risk factors for thromboembolism.

GRADE OF RECOMMENDATION: Work Group Consensus Statement

When indicated, how long should chemoprophylaxis be continued following spinal surgery?

RECOMMENDATION: The available literature does not support an ideal duration for which chemoprophylaxis should be continued following spinal surgery. It is the work group's recommendation that this parameter be decided based upon the underlying pathological condition being treated, co-morbidities (eg, heart valve, previous DVT, stent restenosis prophylaxis), and other host factors, such as ambulatory and neurological status.

GRADE OF RECOMMENDATION: Work Group Consensus Statement

In patients who are being treated with chemical anticoagulants for a non-spine related disorder (eg, valve replacement), what is the ideal "bridge" therapy between stopping and starting the usual agent before and after surgery?

RECOMMENDATION: The literature reviewed does not support an ideal perioperative "bridge" therapy. Candidate agents, such

as warfarin, therapeutic heparin, LMWH, clopidogrel or acetylsalicylic acid (ASA) all increase bleeding risk in postoperative spinal surgery patients. It is the work group's recommendation that the magnitude of surgical insult and underlying thromboembolic risk be balanced against the risk for epidural bleeding and wound complications. Though not substantiated by evidence, the work group agreed that the use of intravenous heparin is a reasonable bridge therapy for those patients being indefinitely treated with warfarin for a non-spine condition. The rationale for this statement is that intravenous heparin is more controllable and more predictable than LMWH, though LMWH is a reasonable alternative bridge therapy. The ideal time to discontinue agents such as clopidogrel and ASA is unique to the pharmacokinetics of the particular medication as it is influenced by the clearance half-life, however, an interval of approximately one week prior to surgery seems prudent.

GRADE OF RECOMMENDATION:
Work Group Consensus Statement

Future Directions for Research

Recommendation #1:
The work group recommends a randomized controlled trial of LMWH vs. heparin as a bridge therapy for patients on long term warfarin prophylaxis for cardiac or other vascular conditions.

Recommendation #2:
The work group recommends a comparative study identifying the risks of perioperative bleeding complications in spinal surgery patients with clopidogrel-coated stents compared with those taking ASA and controls.

Recommendation #3:
The work group recommends a comparative study investigating the rate of bleeding complications in patients discontinuing clopidogrel ten days, seven days and one day prior to elective spinal surgery.

Recommendation #4:
The work group recommends a prospective study investigating optimum duration of postoperative prophylaxis comparing three groups of spine surgery patients treated with LMWH, ASA or clopidogrel for one week and another three groups of patients treated with LMWH, ASA or clopidogrel for four weeks.

Recommendation #5:
The work group recommends a comparative study investigating the incidence of bleeding complications in spinal patients receiving LMWH immediately postoperatively with another group of patients receiving LMWH three days postoperatively.

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D. Wound Complications

Does the use of chemoprophylaxis increase the risk of wound complications or neurologic decline from epidural hematoma in patients receiving chemoprophylaxis after spinal surgery?

A comprehensive review of the spine literature did not yield sufficient evidence to address the question related to the risk of wound complications or neurologic decline from epidural hematoma following use of chemoprophylaxis.

Future Directions for Research

Controlled studies documenting rates of wound complications in spinal surgical patients who received specific chemoprophylaxis protocols are suggested. Data recorded for each patient should include type of procedure as well as specific chemoprophylaxis protocol (chemoprophylaxis agent, dosage, timing and duration).

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E. Risk/Benefit Analysis

What is the ideal measure by which to gauge the risk/benefit ratio of chemoprophylaxis in patients undergoing spinal surgery?

A comprehensive review of the spine literature did not yield sufficient evidence to address the previous question related to the risk of wound complications or neurologic decline from epidural hematoma following use of chemoprophylaxis. With limited evidence on efficacy of chemoprophylaxis, the work group was unable to address this question.

Future Directions for Research

Additional studies are suggested in previous sections of this guideline to both address the efficacy of chemoprophylaxis as well as provide a detailed documentation of rates of wound complications for specific populations and chemoprophylaxis protocols. Until additional information is available to address both of these issues, questions related to risk/benefit analysis cannot be adequately or accurately addressed.

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V. Appendices

Appendix A:
Levels of Evidence for Primary Research Question[1]

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[2] of Level I studies
Level II	• Lesser quality RCT (eg, < 80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level I studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% follow-up.) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[2] of Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[2] of Level III studies
Level IV	Case series[8]	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called "cases"; eg, failed total arthroplasty, are compared to those who did not have outcome, called "controls"; eg, successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

Appendix B:
Grades of Recommendation for Summaries or Reviews of Studies

A: Good evidence (Level I studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Appendix C:
Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care or use of new technologies is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities.

Background

It has become apparent that the number of literature searches being conducted at NASS is increasing and that they are not necessarily conducted in a consistent manner between committees/projects. Because the quality of a literature search directly affects the quality of recommendations made, a comparative literature search was undertaken to help NASS refine the process and make recommendations about how to conduct future literature searches on a NASS-wide basis.

In November-December 2004, NASS conducted a trial run at new technology assessment. As part of the analysis of that pilot process, the same literature searches were conducted by both an experienced NASS member and a medical librarian for comparison purposes. After reviewing the results of that experiment and the different strategies employed for both searches, it was the recommendation of NASS Research staff that a protocol be developed to ensure that all future NASS searches be conducted consistently to yield the most comprehensive results. While it is recognized that some searches occur outside the Research and Clinical Care Councils, it is important that all searches conducted at NASS employ a solid search strategy, regardless of the source of the request. To this end, this protocol has been developed and NASS-wide implementation is recommended.

Protocol for NASS Literature Searches

The NASS Research Department has a relationship with Northwestern University's Galter Health Sciences Library. When it is determined that a literature search is needed, NASS research staff will work with the requesting parties and Galter to run a comprehensive search employing at a minimum the following search techniques:

1. A preliminary search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). The following parameters are to be provided to research staff to facilitate this search.
   - Time frames for search
   - Foreign and/or English language
   - Order of results (chronological, by journal, etc.)
   - Key search terms and connectors, with or without MeSH terms to be employed
   - Age range
   - Answers to the following questions:
     - Should duplicates be eliminated between searches?
     - Should searches be separated by term or as one large package?
     - Should human studies, animal studies or cadaver studies be included?

   This preliminary search should encompass a search of the Cochrane database when access is available.

2. Search results with abstracts will be compiled by Galter in EndNote™ software. Galter typically responds to requests and completes the searches within two to five days. Results will be forwarded to the research staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff have access to EndNote™ software and will maintain a database of search results for future use/documentation.)

3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review and on which to run a "related articles" search.

4. Based on content expert's review, NASS research staff will then coordinate with the Galter medical librarian the second level searching to identify relevant "related articles."

5. Galter will forward results to research staff to share with appropriate NASS staff member.

6. NASS staff share related articles search results with an appropriate content expert (NASS Committee member or other) to assess relevance of this second set of articles, and identify appropriate articles to review and on which to run a second "related articles" search.

7. NASS research staff will work with Galter library to obtain the 2nd related articles search results and any necessary full-text articles for review.

8. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

Protocol for Expedited Searches

At a minimum, numbers 1, 2 and 3 should be followed for any necessary expedited search. Following #3, depending on the time frame allowed, deeper searching may be conducted as described by the full protocol or request of full-text articles may occur. If full-text articles are requested, #8 should also be included. Use of the expedited protocol or any deviation from the full protocol should be documented with explanation.

Following these protocols will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. Research staff will maintain a search history in EndNote,™ for future use or reference.

Appendix D:
Literature Search Parameters
Key Clinical Questions: Search Strategies
Antithrombotic Therapies in Spine Surgery

SUGGESTED SEARCH PARAMETERS FOR ALL QUESTIONS:

- Time frames for search: 1966-PRESENT
- Foreign and/or English language: ENGLISH ONLY
- Order of results (chronological, by journal, etc.): CHRONOLOGICAL
- Key search terms and connectors, with or without MeSH terms to be employed: LISTED WITH EACH QUESTION
- Age range: 18+
- Should duplicates be eliminated between searches? NO
- Should searches be separated by term or as one large package? ONE PACKAGE PER QUESTION
- Should human studies, animal studies or cadaver studies be included? HUMAN STUDIES ONLY

Incidence of DVT or PE in Spine Surgery

Without Antithrombotic Prophylaxis – Work Group 1

1. What is the overall rate (symptomatic and asymptomatic) of DVT or PE following elective spinal surgery without any form of prophylaxis?

   (((“Spine/surgery”[Mesh] OR “Spinal Diseases/surgery”[Mesh] OR “Spinal Fusion”[Mesh] OR “Diskectomy”[Mesh] OR “Laminectomy”[Mesh] OR “Spinal Nerves/surgery”[Mesh] OR “Spinal Cord/surgery”[Mesh] OR “Spinal Cord Diseases/surgery”[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT (“Spinal Cord Injuries/surgery”[Mesh] OR “Spinal Cord Neoplasms/surgery”[Mesh] OR “Spinal Neoplasms/surgery”[Mesh] OR “Spinal Injuries/surgery”[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((“Pulmonary Embolism”[Mesh] OR “Venous Thrombosis”[Mesh]) OR “Thrombophlebitis”[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR DVT[title] AND ((Humans[Mesh]) AND (English[lang])))) NOT ((((“Thrombolytic Therapy”[Mesh] OR “Chemoprevention”[Mesh:noexp]) OR (“Thrombosis/drug therapy”[Mesh] OR “Thrombosis/prevention and control”[Mesh] OR “Thrombosis/therapy”[Mesh])) OR (“Anticoagulants”[Mesh] OR “Anticoagulants “[Pharmacological Action])) OR (“Fibrinolytic Agents”[Mesh] OR “Fibrinolytic Agents “[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND (“humans”[MeSH Terms] AND English[lang])) in PubMed

   Addendum:
   ((“Spine/surgery”[Mesh] OR “Spinal Diseases/surgery”[Mesh] OR “Spinal Fusion”[Mesh] OR “Diskectomy”[Mesh] OR “Laminectomy”[Mesh] OR “Spinal Nerves/surgery”[Mesh] OR “Spinal Cord/surgery”[Mesh] OR “Spinal Cord Diseases/surgery”[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT (“Spinal Cord

Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND (("Pulmonary Embolism"[Mesh] OR "Venous Thrombosis"[Mesh]) OR "Thrombophlebitis"[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR DVT[title] AND ((Humans[Mesh]) AND (English[lang]))) in PubMed

2. What are the relative rates of clinically symptomatic DVT or PE (including fatal PE) without any form or prophylaxis following elective cervical, thoracic and lumbar surgery?

   (((("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND (("Pulmonary Embolism"[Mesh] OR "Venous Thrombosis"[Mesh]) OR "Thrombophlebitis"[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR DVT[title] AND ((Humans[Mesh]) AND (English[lang])))) AND "clinically symptomatic" in PubMed

With Antithrombotic Prophylaxis – Work Group 2

3. What is the rate of clinically symptomatic DVT and/or PE (including fatal PE) following elective spinal surgery with one or more of the following prophylaxis measures: compression stockings, mechanical sequential compression devices, chemoprophylaxis medication?

   (((((("Stockings, Compression"[Mesh] OR "Intermittent Pneumatic Compression Devices"[Mesh])) OR "Bandages"[Mesh]) OR ("venous thrombosis/prevention and control"[Mesh] AND (compression OR bandages OR bandage)) OR compression stockings[all fields] OR compression hose[all fields] OR sequential compression devices[all fields] OR intermittent pneumatic compression[all fields] AND ((Humans[Mesh]) AND (English[lang]))) OR ((((("Thrombolytic Therapy"[Mesh] OR "Chemoprevention"[Mesh:noexp]) OR ("Thrombosis/drug therapy"[Mesh] OR "Thrombosis/prevention and control"[Mesh] OR "Thrombosis/therapy"[Mesh])) OR ("Anticoagulants"[Mesh] OR "Anticoagulants "[Pharmacological Action])) OR ("Fibrinolytic Agents"[Mesh] OR "Fibrinolytic Agents "[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND ("humans"[MeSH Terms] AND English[lang])) AND ((Humans[Mesh]) AND (English[lang]))) AND ((("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND (("Pulmonary Embolism"[Mesh] OR "Venous Thrombosis"[Mesh]) OR "Thrombophlebitis"[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR DVT[title] AND ((Humans[Mesh]) AND (English[lang])))) AND ((Humans[Mesh]) AND (English[lang])) in PubMed

Incidence of DVT or PE in High Risk Patient Populations

Without Antithrombotic Prophylaxis – Work Group 1

4. What is the overall rate (symptomatic and asymptomatic) of DVT or PE in nonsurgically treated acute spine trauma or tumor patients without any form of prophylaxis?

   ((((((“Spinal Injuries”[Mesh] OR “Spinal Neoplasms”[Mesh]) NOT “Spinal Neoplasms/surgery”[Mesh]) NOT “Spinal Injuries/surgery”[Mesh] AND ((Humans[Mesh]) AND (English[lang]))) AND ((“Pulmonary Embolism”[Mesh] OR “Venous Thrombosis”[Mesh]) OR “Thrombophlebitis”[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR DVT[title] AND ((Humans[Mesh]) AND (English[lang]))) AND ((Humans[Mesh]) AND (English[lang]))) NOT ((((“Thrombolytic Therapy”[Mesh] OR “Chemoprevention”[Mesh:noexp]) OR (“Thrombosis/drug therapy”[Mesh] OR “Thrombosis/prevention and control”[Mesh] OR “Thrombosis/therapy”[Mesh])) OR (“Anticoagulants”[Mesh] OR “Anticoagulants “[Pharmacological Action])) OR (“Fibrinolytic Agents”[Mesh] OR “Fibrinolytic Agents “[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND (“humans”[MeSH Terms] AND English[lang])) AND ((Humans[Mesh]) AND (English[lang]))) NOT (spinal neoplasms/secondary AND ((Humans[Mesh]) AND (English[lang]))) AND ((Humans[Mesh]) AND (English[lang]))) NOT (“surgery”[Subheading]) in PubMed

5. What is the overall rate (symptomatic and asymptomatic) of DVT or PE following nonelective spinal surgery for spine trauma or malignancy without any form of prophylaxis?

   ((((“Spinal Neoplasms”[Mesh] OR “Spinal Injuries”[Mesh]) AND “surgery”[subheading]) OR ((tumor[title] OR tumors[title] OR malignancy[title] OR malignancies[title] OR trauma[title]) AND (spinal[all fields] OR (“spine”[MeSH Terms] OR spine[Text Word])))) AND ((“Pulmonary Embolism”[Mesh] OR “Venous Thrombosis”[Mesh]) OR “Thrombophlebitis”[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR deep venous thrombosis[title] OR DVT[title] AND (“humans”[MeSH Terms] AND English[lang]))) NOT ((((“Thrombolytic Therapy”[Mesh] OR “Chemoprevention”[Mesh:noexp]) OR (“Thrombosis/drug therapy”[Mesh] OR “Thrombosis/prevention and control”[Mesh] OR “Thrombosis/therapy”[Mesh])) OR (“Anticoagulants”[Mesh] OR “Anticoagulants “[Pharmacological Action])) OR (“Fibrinolytic Agents”[Mesh] OR “Fibrinolytic Agents “[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND (“humans”[MeSH Terms] AND English[lang])) in PubMed

6. What is the rate of clinically symptomatic DVT or PE (including fatal PE) following nonelective spinal surgery for spine trauma or malignancy without any form of prophylaxis?

   ((((“Spinal Neoplasms”[Mesh] OR “Spinal Injuries”[Mesh]) AND “surgery”[subheading]) OR ((tumor[title] OR tumors[title] OR malignancy[title] OR malignancies[title] OR trauma[title]) AND (spinal[all fields] OR (“spine”[MeSH Terms] OR spine[Text Word])))) AND ((“Pulmonary Embolism”[Mesh] OR “Venous Thrombosis”[Mesh]) OR “Thrombophlebitis”[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR deep venous thrombosis[title] OR DVT[title] AND (“humans”[MeSH Terms] AND English[lang]))) NOT

((((“Thrombolytic Therapy”[Mesh] OR “Chemoprevention”[Mesh:noexp]) OR (“Thrombosis/drug therapy”[Mesh] OR “Thrombosis/prevention and control”[Mesh] OR “Thrombosis/therapy”[Mesh])) OR (“Anticoagulants”[Mesh] OR “Anticoagulants “[Pharmacological Action])) OR (“Fibrinolytic Agents”[Mesh] OR “Fibrinolytic Agents “[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND (“humans”[MeSH Terms] AND English[lang])) in PubMed

With Antithrombotic Prophylaxis – Work Group 2

7. What is the rate of clinically symptomatic DVT and/or PE (including fatal PE) following nonelective spinal surgery for spine trauma or malignancy with one or more of the following prophylaxis measures: compression stockings, mechanical sequential compression devices, chemoprophylaxis medication?

((“Pulmonary Embolism”[Mesh] OR “Venous Thrombosis”[Mesh]) OR “Thrombophlebitis”[Mesh] OR pulmonary embolism[title] OR PE[title] OR deep vein thrombosis[title] OR deep venous thrombosis[title] OR DVT[title] AND (“humans”[MeSH Terms] AND English[lang])) AND (((“Spinal Neoplasms”[Mesh] OR “Spinal Injuries”[Mesh]) AND “surgery”[subheading]) OR ((tumor[title] OR tumors[title] OR malignancy[title] OR malignancies[title] OR trauma[title]) AND (spinal[all fields] OR (“spine”[MeSH Terms] OR spine[Text Word])))) AND (((((“Thrombolytic Therapy”[Mesh] OR “Chemoprevention”[Mesh:noexp]) OR (“Thrombosis/drug therapy”[Mesh] OR “Thrombosis/prevention and control”[Mesh] OR “Thrombosis/therapy”[Mesh])) OR (“Anticoagulants”[Mesh] OR “Anticoagulants “[Pharmacological Action])) OR (“Fibrinolytic Agents”[Mesh] OR “Fibrinolytic Agents “[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND (“humans”[MeSH Terms] AND English[lang])) OR ((((“Stockings, Compression”[Mesh] OR “Intermittent Pneumatic Compression Devices”[Mesh])) OR “Bandages”[Mesh]) OR (“venous thrombosis/prevention and control”[Mesh] AND (compression OR bandages OR bandage)) OR compression stockings[all fields] OR compression hose[all fields] OR sequential compression devices[all fields] OR intermittent pneumatic compression[all fields] AND ((Humans[Mesh]) AND (English[lang])))) in PubMed

Prophylaxis Protocol – Work Group 2

Chemoprophylaxis

8. When indicated, what is the ideal time to begin chemoprophylaxis in relation to spinal surgery?

((“Spine/surgery”[Mesh] OR “Spinal Diseases/surgery”[Mesh] OR “Spinal Fusion”[Mesh] OR “Diskectomy”[Mesh] OR “Laminectomy”[Mesh] OR “Spinal Nerves/surgery”[Mesh] OR “Spinal Cord/surgery”[Mesh] OR “Spinal Cord Diseases/surgery”[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT (“Spinal Cord Injuries/surgery”[Mesh] OR “Spinal Cord Neoplasms/surgery”[Mesh] OR “Spinal Neoplasms/surgery”[Mesh] OR “Spinal Injuries/surgery”[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((((“Thrombolytic Therapy”[Mesh] OR “Chemoprevention”[Mesh:noexp]) OR (“Thrombosis/drug therapy”[Mesh] OR “Thrombosis/prevention and control”[Mesh] OR “Thrombosis/therapy”[Mesh])) OR (“Anticoagulants”[Mesh] OR “Anticoagulants “[Pharmacological Action])) OR (“Fibrinolytic Agents”[Mesh] OR “Fibrin-

olytic Agents "[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND ("humans"[MeSH Terms] AND English[lang])) in PubMed

9. When indicated, how long should chemoprophylaxis be continued following spinal surgery?

   (("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((((("Thrombolytic Therapy"[Mesh] OR "Chemoprevention"[Mesh:noexp]) OR ("Thrombosis/drug therapy"[Mesh] OR "Thrombosis/prevention and control"[Mesh] OR "Thrombosis/therapy"[Mesh])) OR ("Anticoagulants"[Mesh] OR "Anticoagulants "[Pharmacological Action])) OR ("Fibrinolytic Agents"[Mesh] OR "Fibrinolytic Agents "[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND ("humans"[MeSH Terms] AND English[lang])) in PubMed

10. In patients who are being treated with chemical anticoagulants for a non-spine related disorder (eg, valve replacement), what is the ideal "bridge" therapy between stopping and starting the usual agent before and after surgery?

    (("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((((("Thrombolytic Therapy"[Mesh] OR "Chemoprevention"[Mesh:noexp]) OR ("Thrombosis/drug therapy"[Mesh] OR "Thrombosis/prevention and control"[Mesh] OR "Thrombosis/therapy"[Mesh])) OR ("Anticoagulants"[Mesh] OR "Anticoagulants "[Pharmacological Action])) OR ("Fibrinolytic Agents"[Mesh] OR "Fibrinolytic Agents "[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND ("humans"[MeSH Terms] AND English[lang])) in PubMed

Mechanical Prophylaxis

11. When indicated, what is the ideal time to begin mechanical prophylaxis in relation to spinal surgery?

    (("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((((("Stockings, Compression"[Mesh] OR "Intermittent Pneumatic Com-

pression Devices"[Mesh])) OR "Bandages"[Mesh]) OR ("venous thrombosis/prevention and control"[Mesh] AND (compression OR bandages OR bandage)) OR compression stockings[all fields] OR compression hose[all fields] OR sequential compression devices[all fields] OR intermittent pneumatic compression[all fields] AND ((Humans[Mesh]) AND (English[lang]))) in PubMed

12. When indicated, how long should mechanical prophylaxis be continued following spinal surgery?

    (("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((((("Stockings, Compression"[Mesh] OR "Intermittent Pneumatic Compression Devices"[Mesh])) OR "Bandages"[Mesh]) OR ("venous thrombosis/prevention and control"[Mesh] AND (compression OR bandages OR bandage)) OR compression stockings[all fields] OR compression hose[all fields] OR sequential compression devices[all fields] OR intermittent pneumatic compression[all fields] AND ((Humans[Mesh]) AND (English[lang]))) in PubMed

Complications and Risk/Benefit Analysis – Work Group 3

13. Does the use of chemoprophylaxis increase the risk of wound complications or neurologic decline from epidural hematoma in patients receiving chemoprophylaxis after spinal surgery?

    (("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh] OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ((Humans[Mesh]) AND (English[lang]))) NOT ("Spinal Cord Injuries/surgery"[Mesh] OR "Spinal Cord Neoplasms/surgery"[Mesh] OR "Spinal Neoplasms/surgery"[Mesh] OR "Spinal Injuries/surgery"[Mesh]) AND ((Humans[Mesh]) AND (English[lang]))) AND ((((("Thrombolytic Therapy"[Mesh] OR "Chemoprevention"[Mesh:noexp]) OR ("Thrombosis/drug therapy"[Mesh] OR "Thrombosis/prevention and control"[Mesh] OR "Thrombosis/therapy"[Mesh])) OR ("Anticoagulants"[Mesh] OR "Anticoagulants "[Pharmacological Action])) OR ("Fibrinolytic Agents"[Mesh] OR "Fibrinolytic Agents "[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Hematoma, Epidural, Cranial"[Mesh] OR "Hematoma, Epidural, Spinal"[Mesh] OR epidural hematoma[title] AND ((Humans[Mesh]) AND (English[lang]))) AND ((Humans[Mesh]) AND (English[lang])) in PubMed

14. What is the ideal measure by which to gauge the risk/benefit ratio of chemoprophylaxis in patients undergoing spinal surgery?

    (("Spine/surgery"[Mesh] OR "Spinal Diseases/surgery"[Mesh] OR "Spinal Fusion"[Mesh]

OR "Diskectomy"[Mesh] OR "Laminectomy"[Mesh] OR "Spinal Nerves/surgery"[Mesh] OR "Spinal Cord/surgery"[Mesh] OR "Spinal Cord Diseases/surgery"[Mesh] OR spine surgery[title] OR spinal surgery[title] AND ("humans"[MeSH Terms] AND English[lang])) AND ((((("Thrombolytic Therapy"[Mesh] OR "Chemoprevention"[Mesh:noexp]) OR ("Thrombosis/drug therapy"[Mesh] OR "Thrombosis/prevention and control"[Mesh] OR "Thrombosis/therapy"[Mesh])) OR ("Anticoagulants"[Mesh] OR "Anticoagulants "[Pharmacological Action])) OR ("Fibrinolytic Agents"[Mesh] OR "Fibrinolytic Agents "[Pharmacological Action] OR anticoagulation[title] OR antithrombotic[title] OR chemoprophylaxis[title]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("humans"[MeSH Terms] AND English[lang])) AND (((("Risk Assessment"[Mesh] OR ("Risk"[Mesh] OR "Risk Reduction Behavior"[Mesh] OR "Risk Factors"[Mesh]) OR risk[title] OR benefit[title]) OR ("Outcome Assessment (Health Care)"[Mesh] OR "Treatment Outcome"[Mesh])) OR "Epidemiologic Measurements"[Mesh] AND ("humans"[MeSH Terms] AND English[lang])) AND ("humans"[MeSH Terms] AND English[lang]) in PubMed

Appendix E:
Evidentiary Tables

INCIDENCE OF DVT/PE IN SPINE SURGERY

■ What is the overall rate (symptomatic and asymptomatic) of DVT or PE following elective spinal surgery without any form of prophylaxis?

Article (Alpha by Author)	Level (I-V) Type of evidence	Description of study	Conclusion	Explanation of failure to meet guideline inclusion criteria *(when applicable)*
Gruber UF, Rem J, Meisner C, Gratzl O. Prevention of thromboembolic complications with miniheparin-dihydroergotamine in patients undergoing lumbar disc operations. Eur Arch Psychiatry Neurol Sci. 1984;234(3):157-161.	Level III Type of evidence: prognostic	☒Prospective ☐Retrospective – check one Study design (select one): comparative Stated objective of study: Determine the incidence of bleeding complications in patients undergoing lumbar spine surgery treated with minidose heparin-DHE compared with those receiving placebo. Total number of patients: 50 Number of patients not receiving prophylaxis: 20 (5 patients in the control group of 25 were found to have received heparin at another hospital) Duration of follow-up: 7 days	*Critique of methodology* ☒Patients not enrolled at same point in their disease ☐<80% follow-up ☒No validated outcome measures used ☒Small sample size ☐Lacked subgroup analysis ☒Diagnostic method(s) not described ☐Follow-up was not standardized. ☒Other: only performed test on patients with clinically suspicious presentation *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): III *Conclusions relative to question* This paper provides evidence that:in this	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Validated outcome measures used (list): Ultrasound or I125 scan, only performed, however, on patients in whom clinical findings (not described) suggested possible DVT Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☒ Other (please specify): 125 Fibrinogen, CXR, EEG, VQ Scan, pulmonary angiogram if PE suspect Results/subgroup analysis (relevant to question): Incidence of DVT: Zero Incidence of PE: Zero Other: Author conclusions (relative to question): In this small series of consecutive patients undergoing "lumbar disc operations," no clinically evident DVT or PE events were documented.	small series of consecutive patients undergoing "lumbar disc operations," no clinically evident DVT or PE events were documented.	
Joffe SN.	Level V	☒Prospective ☐Retrospective – check	*Critique of methodology*	*Justification*

Incidence of postoperative deep vein thrombosis in neurosurgical patients. J Neurosurg. Feb 1975;42(2):201-203.	Type of evidence: prognostic	one Study design (select one): case series Stated objective of study: Investigate the incidence of DVT in patients undergoing elective neurosurgical procedures. Total number of patients: 23 (only 10 spinal cases) Number of patients not receiving prophylaxis: 23 (10 spinal cases) Duration of follow-up: Hospitalization (greater than 7 days) Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☒ Other (please specify): I-125 Fibrinogen Results/subgroup analysis (relevant to	☐Patients not enrolled at same point in their disease ☐<80% follow-up ☐No validated outcome measures used ☒Small sample size ☐Lacked subgroup analysis ☐Diagnostic method(s) not described *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): V *Conclusions relative to question* This paper provides evidence that:asymptomatic DVT is not uncommon in a nonselect group of patients undergoing elective spinal surgery followed by a prolonged period of postoperative bedrest. The applicability of these findings today is questionable given that prolonged periods of bed rest are no longer recommended following surgery. The paper also suggests that clinical manifestations are not reliable for the diagnosis of DVT.	*(check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		question): Incidence of DVT: 60%, 6/10 with spinal surgery Incidence of PE: not stated Other: Author conclusions (relative to question): Neurosurgical patients are at risk for DVT; these patients are often asymptomatic. DVT will be underdiagnosed by clinical criteria alone, but this conclusion was based on a mix of cranial and spinal data.		
Lee HM, Suk KS, Moon SH, Kim DJ, Wang JM, Kim NH. Deep vein thrombosis after major spinal surgery: incidence in an East Asian population. Spine. Jul 15 2000;25(14):1827-1830.	Level II Type of evidence: prognostic	☒Prospective ☐Retrospective – check one Study design (select one): comparative Stated objective of study: To determine the rate of DVT after elective spinal surgery (without prophylaxis) in an east Asian (Korean) population. Total number of patients: 313 Number of patients not receiving prophylaxis: 313 Duration of follow-up: 5 to 7 days Validated outcome measures used (list): ultrasound	*Critique of methodology* ☒Patients not enrolled at same point in their disease ☐<80% follow-up ☐No validated outcome measures used ☐Small sample size ☒Lacked subgroup analysis ☐Diagnostic method(s) not described ☒Other: included an unknown number of pediatric patients with subgroup analysis not provided *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:in this series of east Asian patients who	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☒Subgroup analysis data not available ☐Not relevant to question

		Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: The overall incidence of thrombotic complications was 1.3% and the incidence of symptomatic DVT was 0.3% Incidence of PE: none clinically seen Other: Some patients were pediatric. Author conclusions (relative to question): East Asians do not get DVT often enough to warrant prophylaxis. Routine screening and prophylaxis for the east Asian patients undergoing elective spinal surgery is not warranted.	underwent elective spinal surgery without antithrombotic prophylaxis, a very low rate of DVT was observed, using ultrasound screening. Although the authors concluded that these results were related to the ethnicity of the patient group, it is possible that other unidentified factors (other than ethnicity) may have had a role in this finding.	
Oda T, Fuji T, Kato Y, Fujita S, Kanemitsu N. Deep venous thrombosis after	Level II Type of evidence: prognostic	☒Prospective ☐Retrospective – check one Study design (select one): comparative	*Critique of methodology* ☒Patients not enrolled at same point in their disease ☐<80% follow-up ☐No validated outcome measures used	*Justification (check all that apply):* ☐Level V (expert

posterior spinal surgery. Spine. Nov 15 2000;25(22):2962-2967.		Stated objective of study: To document the prevalence of DVT after posterior spinal surgery with no prophylaxis Total number of patients: 134/110 studied with venography Number of patients not receiving prophylaxis: 134 Duration of follow-up: Venography performed within 14 days of surgery (average 7.2 days). Clinical follow-up of at least 3 months. Validated outcome measures used (list): venography Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 17/110 (15.5%) had venographic evidence of DVT;	☐Small sample size ☐Lacked subgroup analysis ☐Diagnostic method(s) not described *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): *Conclusions relative to question* *This paper provides evidence that:*the rate of DVT in postoperative spine surgery patients may be underestimated. Clinical manifestations are not reliable for the diagnosis of DVT. Increased age and posterior approach to the lumbar spine are risk factors. It should be noted that all patients had an interval of bed rest following surgery.	consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		0/110 patients had clinical manifestations of DVT. Incidence of PE: none Other: The prevalence of DVT after posterior spinal surgery: lumbar 26.5% > thoracic 14.3% > cervical 5.6%. Increased age is a risk factor for DVT. Author conclusions (relative to question): The prevalence of DVT after posterior spinal surgery is higher than generally recognized (15.5%); therefore, further study is necessary to clarify the appropriate method for screening and the efficacy of DVT prophylaxis after spinal surgery.		
Uden A. Thromboembolic complications following scoliosis surgery in Scandinavia. Acta Orthop Scand. Apr 1979;50(2):175-178.	Level IV Type of evidence: prognostic	☐Prospective ☒Retrospective – check one Study design (select one): case series Stated objective of study: to document the rate of clinically evident DVT in a population of patients treated surgically with Harrington instrumentation and 3 to 5 weeks of bed rest. Total number of patients: 1229 Number of patients not receiving prophylaxis: 1229	*Critique of methodology* ☒Patients not enrolled at same point in their disease ☐<80% follow-up ☐No validated outcome measures used ☐Small sample size ☒Lacked subgroup analysis ☒Diagnostic method(s) not described ☒Other: Some patients had 2 separate surgeries with this subgroup analysis data not provided. Variable diagnostic methods implemented, but no standardized follow up or duration identified.	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Duration of follow-up: at least 5 weeks Validated outcome measures used (list): venography was used, but only on patients who had clinical findings. They also used autopsy findings. Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☒ Other (please specify): Contrast phlebography, isotope phlebography, autopsy Results/subgroup analysis (relevant to question): Incidence of DVT: 8/1229 (0.65%) Incidence of PE: 1/1229 (0.08%) Other: All 8 DVTs were proximal on the left side. The incidence of thromboembolic complications increases with age and the number of vertebrae fused. Patients may present with pain in the leg or lower abdominal region. PE may occur with minimal clinical evidence of DVT.	*Work group conclusions* Potential Level (select one): III Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:clinically evident DVT can occur in scoliosis patients managed with postoperative bed rest.	

		Author conclusions (relative to question): Incidence is low in this group of patients but probably higher than stated (venography done only when clinical diagnosis was made).		

INCIDENCE OF DVT/PE IN SPINE SURGERY

■ What are the relative rates of clinically symptomatic DVT or PE (including fatal PE) without any form or prophylaxis following elective cervical, thoracic, and lumbar surgery?

Article (Alpha by Author)	Level (I-V) Type of evidence	Description of study	Conclusion	Explanation of failure to meet guideline inclusion criteria *(when applicable)*
Lee HM, Suk KS, Moon SH, Kim DJ, Wang JM, Kim NH. Deep vein thrombosis after major spinal surgery: incidence in an East Asian population. Spine. Jul 15 2000;25(14):1827-1830.	Level II Type of evidence: prognostic	☒Prospective ☐Retrospective – check one Study design (select one): comparative Stated objective of study: To determine the rate of DVT after elective spinal surgery(without prophylaxis) in an east Asian (Korean) population. Total number of patients: 313 Number of patients not receiving prophylaxis: 313 Duration of follow-up: 5 to 7 days Validated outcome measures used (list): ultrasound	*Critique of methodology* ☒Patients not enrolled at same point in their disease ☐<80% follow-up ☐No validated outcome measures used ☐Small sample size ☒Lacked subgroup analysis ☐Diagnostic method(s) not described *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:In this series of east Asian patients who underwent elective spinal surgery without	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: The incidence of symptomatic DVT was 0.3% (1/313) Incidence of PE: 0 Other: Some patients were pediatric. Author conclusions (relative to question): East Asians do not get DVT often enough to warrant prophylaxis. Routine screening and prophylaxis for the east Asian patients undergoing elective spinal surgery is not warranted.	antithrombotic prophylaxis, a very low rate of clinically symptomatic DVT was observed, using ultrasound screening. Although the authors concluded that these results were related to the ethnicity of the patient group, it is possible that other unidentified factors (other than ethnicity) may have had a role in this finding.	
Oda T, Fuji T, Kato Y, Fujita S, Kanemitsu N. Deep venous thrombosis after posterior spinal	Level II Type of evidence: prognostic	☒Prospective ☐Retrospective – check one Study design (select one): comparative Stated objective of study: To document the	*Critique of methodology* ☒Patients not enrolled at same point in their disease ☐<80% follow-up ☐No validated outcome measures used ☐Small sample size	*Justification (check all that apply):* ☐Level V (expert consensus)

surgery. Spine. Nov 15 2000;25(22):2962-2967.		prevalence of DVT after posterior spinal surgery with no prophylaxis Total number of patients: 134/110 studied with venography Number of patients not receiving prophylaxis: 134 Duration of follow-up: Venography performed within 14 days of surgery (average 7.2 days). Clinical follow-up of at least 3 months. Validated outcome measures used (list): venography Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 17/110 (15.5%) had venographic evidence of DVT; 0/110 patients had clinical manifestations of DVT.	☐Lacked subgroup analysis ☐Diagnostic method(s) not described *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): *Conclusions relative to question* This paper provides evidence that:clinically evident DVT can be very low post spinal surgery, although the rate of clinically silent DVT can be significant. Clinical exam is not reliable in the diagnosis of DVT in the postoperative spinal surgery patient.	☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Incidence of PE: none Other: The prevalence of DVT after posterior spinal surgery: lumbar 26.5% > thoracic 14.3% > cervical 5.6%. Increased age is a risk factor for DVT. Author conclusions (relative to question): DVT was venographically evident in 3/54 patients (5.6%) who underwent cervical procedures. DVT was evident in 13/49 patients (26.5%) who underwent lumbar procedures. These differences were statisticaly significant. Increased age was established as a risk factor. The prevalence of DVT after posterior spinal surgery is higher than generally recognized (15.5%); therefore, further study is necessary to clarify the appropriate method for screening and the efficacy of DVT prophylaxis after spinal surgery.		

INCIDENCE OF DVT/PE IN SPINE SURGERY

■ **What is the rate of clinically symptomatic DVT and/or PE (including fatal PE) following elective spinal surgery with one or more of the following prophylaxis measures: compression stockings, mechanical sequential compression devices, chemoprophylaxis medication? (PROGNOSTIC QUESTION)**

EFFICACY OF ANTITHROMBOTIC THERAPIES IN SPINE SURGERY

■ **Do prophylactic antithrombotic measures, including compression stockings, mechanical sequential compression devices and chemoprophylaxis medications, decrease the rate of clinically symptomatic DVT and/or PE (including fatal PE) following elective spinal surgery? (THERAPEUTIC QUESTION)**

Article (Alpha by Author)	Level (I-V) Type of evidence	Description of study	Conclusion	Explanation of failure to meet guideline inclusion criteria *(when applicable)*
Dearborn JT, Hu SS, Tribus CB, Bradford DS. Thromboembolic complications after major thoracolumbar spine surgery. Spine. Jul 15 1999;24(14):1471-1476.	Level II Type of evidence: prognostic ~~~~~~~ Level IV Type of evidence therapeutic	☒Prospective ☐Retrospective -- (check one) Study design (select one): comparative Stated objective of study: To determine the incidence of symptomatic and asymptomatic venous thromboembolism by PE or DVT after thoracolumbar fusion surgery. Type(s) of prophylaxis: Mechanical: stockings or pneumatic compression stockings.	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available

		Total number of patients: 116 Number of patients in relevant subgroups: 49 A/P (circumferential) surgery with 67 unilateral (62 PSF/3 ASF/ 2 hardware removal) Consecutive series (select one)? Yes Type(s) of surgery: ASF/PSF/Circumferential or hardware removal Duration of follow-up: 3-20 days for duplex with 2-year retrospective review of group Validated outcome measures used (list): Duplex Doppler and V/Q in 73/116; no clear functional outcome measure used Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☒ Other (please specify): Ventilation-perfusion (V/Q) scans in 73/116,	☐ *Other:* **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:combined posterior and anterior spinal procedures had a greater incidence of PE than posterior only cases using elastic stockings and pneumatic compression as prophylaxis. None of the patients with PE had been identified by Doppler ultrasound as having DVT, so this DVT screening may not be useful for looking at PE in this population. Anterior surgery was a definite risk factor, and there was a trend for older age to be a risk factor. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): III Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:the region and degree/type of spinal surgery should play a role in prophylaxis	☐ Not relevant to question

		Results/subgroup analysis (relevant to question): Incidence of DVT: 0.9% (in retrospective group, 0.3%) Incidence of PE: 2.6% (in retrospective group, 2.5%) Incidence of Tx Related Complications: Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): Duplex ultrasounds appear insensitive to identifying clots in patients subsequently diagnosed with PE. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Simple mechanical prophylaxis for thromboembolism, which may be adequate for patients undergoing posterior procedures, may not be as protective for patients undergoing combined anterior/posterior spine surgery.	choice.	
Epstein NE. Intermittent pneumatic compression stocking prophylaxis	Level II Type of evidence: prognostic	☒Prospective ☐Retrospective -- (check one) Study design (select one): comparative Stated objective of study: To examine the	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers	*Justification (check all that apply):* ☐Level V (expert consensus)

against deep venous thrombosis in anterior cervical spinal surgery: a prospective efficacy study in 200 patients and literature review. Spine. Nov 15 2005;30(22):2538-2543.	~~~~~~~ Level IV Type of evidence: therapeutic	incidence of VTE after one-level and multi-level cervical corpectomy. Type(s) of prophylaxis: Intermittent pneumatic compression stockings Total number of patients: 200 Number of patients in relevant subgroups: 100 one-level, 100 multi-level corpectomies Consecutive series (select one)? Yes Type(s) of surgery: Cervical corpectomy Duration of follow-up: 2 days post-op; 2.5 year one-level, 5.3 year multi-level Validated outcome measures used (list): None Nonvalidated outcome measures used (list): None Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☒ Other (please specify): CT angiogram of chest on patients with suspected PE	☒Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒*Other:* Downgraded due to short follow-up of two days. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:mechanical prophylaxis is associated with a 1-7% risk of DVT and 0-2% risk of PE depending on type of cervical surgery. The study of prognosis did not stratify for other high-risk factors (age, smoking). **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence	☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Results/subgroup analysis (relevant to question): Incidence of DVT: 1% one-level, 7% multi-level Incidence of PE: 0% one-level, 2% multi-level Incidence of Tx Related Complications: 0% Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): The rates of DVT (1% and 7%, respectively) and PE (1% and 2%, respectively) were comparable with frequencies encountered in other cranial/spinal series using mini-heparin and/or low-dose heparin regimens but avoided the 2% to 4% risk of major postoperative hemorrhage. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Intermittent compression pneumatic stockings were equally effective to literature reported rates of prophylaxis with low-dose heparin and avoided the risks of post-operative hemorrhage.	that:Mechanical prophylaxis is an attractive option given that there is a risk of hemorrhage after surgery with heparin.	
Epstein NE. Efficacy of pneumatic compression	Level IV Type of evidence:	☐Prospective ☒Retrospective -- (check one) Study design (select one): case series	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☒Nonconsecutive patients	*Justification (check all that apply):* ☐Level V

stocking prophylaxis in the prevention of deep venous thrombosis and pulmonary embolism following 139 lumbar laminectomies with instrumented fusions. J Spinal Disord Tech. Feb 2006;19(1):28-31.	prognostic ~~~~~~~ Level IV Type of evidence therapeutic	Stated objective of study: To examined the incidence of VTE with pneumatic compression stockings Type(s) of prophylaxis: Pneumatic compression stockings Total number of patients: 139 Number of patients in relevant subgroups: None Consecutive series (select one)? No Type(s) of surgery: Lumbar laminectomies with fusion Duration of follow-up: Postoperative period Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify):	☒Nonrandomized ☒Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☒Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒*Other:* Unable to ascertain whether this was a prospective study, thus the work group had to assume it was retrospective. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:With lumbar decompression and stabilization, mechanical prophylaxis has low rate of VTE. Incidence of DVT following elective decompression and fusion in patients wearing SCD postoperatively was 2.9%. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV	(expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Results/subgroup analysis (relevant to question): Incidence of DVT: 2.9% (4/139) Incidence of PE: 0.7% (1/139) Incidence of Tx Related Complications: Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): The rate of DVT is 2.9% in elective lumbar decompressions and fusion when using compression stockings for prophylaxis. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Pneumatic compression stockings provided effective prophylaxis for DVT in elective lumbar fusion surgery, almost comparable to low-dose heparin regimens without the associated risk of hematomas and neurological compromise.	Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:mechanical prophylaxis with elective lumbar surgery minimizes DVT risk.	
Ferree BA. Deep venous thrombosis following lumbar laminotomy and laminectomy. Orthopedics. Jan	Level II Type of evidence: prognostic ~~~~~~~	☒Prospective ☐Retrospective -- (check one) Study design (select one): comparative Stated objective of study: Investigate the incidence of DVT after lumbar	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in

1994;17(1):35-38.	Level IV Type of evidence: therapeutic	decompressive surgery Type(s) of prophylaxis: Sequential compression stockings Total number of patients: 60 Number of patients in relevant subgroups: 6 patients were greater than 62 years old and 54 were less than 62 years old Consecutive series (select one)? Yes Type(s) of surgery: lumbar laminotomy and laminectomy with some fusion Duration of follow-up: Studies within 14 days preoperatively and 2-5 days postoperatively Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify):	☐No validated outcome measures used ☒Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐*Other:* **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that: DVT is more common in older patients and there is a 5% incidence of Doppler-identified, but asymptomatic DVT on Doppler surveillance in elective laminectomy and laminotomy with compression stockings. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:mechanical prophylaxis via sequential compression stockings is	presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Results/subgroup analysis (relevant to question): Incidence of DVT: 5% (3/60). Age stratified results: in the six patients greater than 62 years of age, there were two DVTs; of the 54 patients under 62 years old, there was only one DVT ($p<.05$). Incidence of PE: none described Incidence of Tx Related Complications: Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): Clinically significant DVT after lumbar decompression appears unusual **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Mechanical prophylaxis in the setting of lumbar decompression appears as an attractive alternative.	effective in reducing thromboembolism in elective laminectomy and laminotomy.	
Ferree BA, Stern PJ, Jolson RS, Roberts JMt, Kahn A, 3rd. Deep venous thrombosis after spinal surgery. Spine. Mar 1	Level II Type of evidence: prognostic ~~~~~~~	☐Prospective ☒Retrospective -- (check one) Study design (select one): comparative Stated objective of study: Determine the incidence of DVT after spine surgery	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☐No validated outcome measures	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of

1993;18(3):315-319.	Level IV Type of evidence: therapeutic	Type(s) of prophylaxis: Pneumatic compression stockings Total number of patients: 86 Number of patients in relevant subgroups: 86 Consecutive series (select one)? Yes Type(s) of surgery: Lumbar and thoracic decompressions (40) with additional fusion (46) Duration of follow-up: Studies within 14 days preoperatively and 7 days postoperatively Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question):	used ☐ Small sample size ☐ <80% follow-up ☐ Lacked subgroup analysis ☐ Diagnostic method(s) not detailed ☒ Other: Since not clearly articulated, the work group was required to assume that this was a retrospective study. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:there is a low incidence of DVT in patients treated with pneumatic compression stockings. Age does not appear to correlate with increased incidence of DVT. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:pneumatic compression stockings	higher quality studies ☐ Subgroup analysis data not available ☐ Not relevant to question

		Incidence of DVT: 6% Incidence of PE: 0% Incidence of Tx Related Complications: 0% Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): Pneumatic compression stockings are effective in preventing DVT. Age does not appear to correlated with DVT **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Pneumatic compression stockings are effective in preventing DVT.	are effective in preventing DVT.	
Ferree BA, Wright AM. Deep venous thrombosis following posterior lumbar spinal surgery. Spine. Jun 15 1993;18(8):1079-1082.	Level III Type of evidence: prognostic ~~~~~~~ Level IV Type of evidence: therapeutic	☐Prospective ☒Retrospective -- (check one) Study design (select one): comparative Stated objective of study: determine the incidence of DVT/PE comparing the use of elastic stockings to intermittent pneumatic compression boots Type(s) of prophylaxis: elastic stockings versus intermittent pneumatic compression stockings Total number of patients: 185	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☒Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☒No validated outcome measures used ☐Small sample size ☐<80% follow-up ☒Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒Other: heterogeneous prophylaxis methods and heterogeneous patient	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Number of patients in relevant subgroups: 74 patients received elastic stockings and 111 received intermittent pneumatic compression (differed by surgeon) Consecutive series (select one)? No Type(s) of surgery: lumbar laminectomies and lumbar fusions Duration of follow-up: 2-7 days postoperatively Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 5% in the elastic stocking group; 0% in the IPC group Incidence of PE: 0%	populations. Selection bias: one surgeon used one method and one used another. Also, groups were not balanced with respect to type of surgery (decompression versus decompression and fusion). **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): III *Conclusions relative to question* This paper provides evidence that:the use of IPC boots appears to significantly lower the incidence of DVT. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): III Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:IPC boots can significantly lower the incidence of DVT.	

		Incidence of Tx Related Complications: 0% Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): No correlation between operation type, length of bed rest, age, tobacco use, or length of procedure and incidence of DVT. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): IPC are more effective than elastic stocking in preventing DVT ($p<0.05$). No differences in DVT by operation type, length of bed rest, age, tobacco use or length of procedure.		
Gerlach R, Raabe A, Beck J, Woszczyk A, Seifert V. Postoperative nadroparin administration for prophylaxis of thromboembolic events is not associated with an increased risk of hemorrhage after spinal surgery. Eur	Level II Type of evidence: prognostic ~~~~~~~ Level IV Type of evidence therapeutic	☐Prospective ☒Retrospective -- (check one) Study design (select one): case series Stated objective of study: Evaluate the incidence of clinically significant hematoma after use of anticoagulation. Type(s) of prophylaxis: Nadroparin + compression stockings Total number of patients: 1954 Number of patients in relevant subgroups: cervical surgery 503, thoracic 152, lumbar	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☒Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐*Other:*	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

Spine J. Feb 2004;13(1):9-13.		1299 Consecutive series (select one)? No Type(s) of surgery: Any spinal surgery in any region Duration of follow-up: Duration of hospitalization Validated outcome measures used (list): Nonvalidated outcome measures used (list): Neurological exam Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☒ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0.05% (1/1954) Incidence of PE: 0% Incidence of Tx Related Complications: 0.4% (8/1954); total hematomas=13 (5 prior to nadroparin) Other:	**PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:there is a very low incidence of DVT/PE in this retrospectively selected patient population which received nadroparin for anticoagulation and compression stockings. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:use of nadroparin and compression stockings results in a very low incidence of DVT/PE with no increased risk of hematoma.	

		PROGNOSTIC ASSESSMENT Author conclusions (relative to question): Early nadroparin is safe and does not appear to increase hematoma risk. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Early nadroparin is safe and does not appear to increase hematoma risk.		
Gruber UF, Rem J, Meisner C, Gratzl O. Prevention of thromboembolic complications with miniheparin-dihydroergotamine in patients undergoing lumbar disc operations. Eur Arch Psychiatry Neurol Sci. 1984;234(3):157-161. Evaluted only to address the incidence of	Level II Type of evidence: prognostic ~~~~~~~ Level Type of evidence: therapeutic	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: Evaluate the incidence of bleeding complications using miniheparin starting preoperatively compared to none in a control group Type(s) of prophylaxis: heparin DHE 2500 Total number of patients: 50 Number of patients in relevant subgroups: n=25 heparin DHE 2500 BID Consecutive series (select one)? Yes Type(s) of surgery: lumbar discectomy	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☒Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐*Other:* **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

DVT/PE, rather than therapeutic efficacy.		Duration of follow-up: until discharge or up to 7 days postoperatively Validated outcome measures used (list): Intraoperative bleeding by volume Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☒ Venography ☒ Other (please specify): I125 fibrinogen; V/Q scan or pulmonary angiogram. Results/subgroup analysis (relevant to question): Incidence of DVT: 4% (1/25) with heparin and 0% (0/25) without Incidence of PE: 0 Incidence of Tx Related Complications: 24% (6/25) with heparin and 28% (7/25) without Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): None **THERAPEUTIC ASSESSMENT**	*Conclusions relative to question* This paper provides evidence that:preoperatively and postoperatively administered miniheparin DHE (2500u bid) did not increase bleeding complications nor did this method of chemoprophylaxis result in decreased incidence of DVT/PE when compared with controls. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): Downgraded Level (select one): *Conclusions relative to question* This paper provides evidence that:.	

		Author conclusions (relative to question): Pre- and postoperative heparinization @ 2500u bid with DHE does not increase bleeding complications.		
Leon L, Rodriguez H, Tawk RG, Ondra SL, Labropoulos N, Morasch MD. The prophylactic use of inferior vena cava filters in patients undergoing high-risk spinal surgery. Ann Vasc Surg. May 2005;19(3):442-447.	Level IV Type of evidence: prognostic ~~~~~~~ Level IV Type of evidence: therapeutic	☐Prospective ☒Retrospective -- (check one) Study design (select one): case series Stated objective of study: Determine if inferior vena cava filters (IVCF) reduce the incidence of PE in a patient population at high risk for VTE. Type(s) of prophylaxis: elastic stockings, pneumatic compression boots, IVCF Total number of patients: 74 Number of patients in relevant subgroups: Stratified by risk factors I (n=4), II (n=19), III (n=19), IV (n=18), V (n=8), VI (n=6) Consecutive series (select one)? No Type(s) of surgery: Major spinal surgery Duration of follow-up: 11 months consisting of weekly Doppler ultrasound while in the hospital and 1 month clinical follow-up standardized	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☒Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☒Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒Other: no subgroup analysis data provided on which patients received prophylaxis in addition to IVCF **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:IVCF are associated with a low incidence of PE in patients at high risk for VTE.	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Validated outcome measures used (list): none Nonvalidated outcome measures used (list): none Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☒ Other (please specify): Abdominopelvic CT and Chest CTA in some patinets Results/subgroup analysis (relevant to question): Incidence of DVT: 31% (23/74) Incidence of PE: 1.3% (1/74) Incidence of Tx Related Complications: misplaced IVCF in 2 patients Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): Incidence of DVT is elevated in this high risk group. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): IVC filters minimize the incidence of PE	**THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:IVCF can significantly reduce the incidence of PE in patients at high risk for VTE.	

Nelson LD, Jr., Montgomery SP, Dameron TB, Jr., Nelson RB. Deep vein thrombosis in lumbar spinal fusion: a prospective study of antiembolic and pneumatic compression stockings. J South Orthop Assoc. Fall 1996;5(3):181-184.	Level II Type of evidence: prognostic ~~~~~~~ Level II Type of evidence: therapeutic	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: To evaluate incidence of DVT following degenerative lumbar spine surgery in patients using TED stockings and acetylsalicylic acid (ASA) compared with those using TED stockings, pneumatic compression boots and ASA (group II) during surgery Type(s) of prophylaxis: TED, pneumatic compression boots and ASA Total number of patients: 117 Number of patients in relevant subgroups: 60 with stockings and ASA 600 mg bid and 57 with stockings and boots plus ASA 600 mg bid Consecutive series (select one)? Yes Type(s) of surgery: posterior lumbar decompression with fusion and fixation Duration of follow-up: 2-6 days postoperatively	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☒Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☒Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒Other: Method of randomization not clearly stated: authors do not state the randomization technique; therefore, it is uncertain how allocation was concealed. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:elastic stockings along with ASA sufficiently reduce the DVT risk. **THERAPEUTIC ASSESSMENT** *Work group conclusions*	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0 Incidence of PE: 0 Incidence of Tx Related Complications: None Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): The use of elastic stockings and ASA 600mg bid is satisfactory for DVT prophylaxis **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): The use of elastic stockings and ASA 600mg bid is satisfactory for DVT prophylaxis	Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:the use of TED stockings and ASA 600 mg is effective in reducing the risk of DVT. Pneumatic compression stockings do not provide additional prophylactic benefits.	

Rokito SE, Schwartz MC, Neuwirth MG. Deep vein thrombosis after major reconstructive spinal surgery. Spine. Apr 1 1996;21(7):853-858; discussion 859.	Level II Type of evidence: prognostic ~~~~~~~ Level III Type of evidence: therapeutic	☒Prospective ☒Retrospective -- (check one) Study design (select one): comparative Stated objective of study: determine the incidence of deep vein thrombosis after major adult spinal surgery and the optimal mode of prophylaxis in this surgical population. Type(s) of prophylaxis: compression stockings, IPC devices, low-dose Coumadin Total number of patients: 329 patients. Number of patients in relevant subgroups: 110 patients were prospectively randomized to one of three study groups. Group 1 (42 patients) received bilateral thigh-high thrombosis embolic deterrent (TED) compression stockings. Group 2 (33 patients) received TED stockings and thigh-length cuffs that provided sequential pneumatic compression to the calf and thigh. Group 3 (35 patients) received TED stockings and low-dose Coumadin. The 219 not randomized received either TED stockings alone or TED stockings and pneumatic compression boots for DVT prophylaxis.	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☒Nonmasked patients ☐No validated outcome measures used ☒Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒Other: Unstated randomization process. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that: Pneumatic compression stockings with TEDS and/or TEDS alone are associated with a low incidence of DVT. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): II Downgraded Level (select one): III	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Consecutive series (select one)? Yes Type(s) of surgery: Anterior and/or posterior spinal fusions and/or decompression Duration of follow-up: 5-7 days for ultrasound and 1 year clinically Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0.3% overall (1/329), 0% in RCT Incidence of PE: 0 Incidence of Tx Related Complications: 5.7% (2/35) with Coumadin but 0% without Other: **PROGNOSTIC ASSESSMENT**	*Conclusions relative to question* This paper provides evidence that:low-dose Coumadin is no more effective than mechanical prophylaxis in reducing DVT risks. Given the increased risk of hemorrhage with Coumadin, mechanical prophylaxis with graduated compression stockings and pneumatic compression boots is preferable to anticoagulation therapy.	

		Author conclusions (relative to question): Pneumatic compression boots and TEDS were associated with a low incidence of DVT/PE. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Pneumatic compression boots and TEDS provide sufficient VTE prophylaxis.		
Smith MD, Bressler EL, Lonstein JE, Winter R, Pinto MR, Denis F. Deep venous thrombosis and pulmonary embolism after major reconstructive operations on the spine. A prospective analysis of three hundred and seventeen patients. J Bone Joint Surg Am. Jul 1994;76(7):980-985.	Level II Type of evidence: prognostic ~~~~~~~ Level IV Type of evidence: therapeutic	☒Prospective ☐Retrospective -- (check one) Study design (select one): case series Stated objective of study: Examine the incidence in complex spine surgery of VTE with compression stockings and pneumatic boots Type(s) of prophylaxis: compression stockings and pneumatic boots Total number of patients: 317 (126 received USG and 191 did not) Number of patients in relevant subgroups: Cervical lesion (32), Infection (3), Lumbar lesion (122), Scoliosis (77), Spinal trauma (34), Spondylolisthesis (31), Thoracic lesion (18)	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☒Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☒No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☒Diagnostic method(s) not detailed ☐*Other:* Inconsistently applied diagnostic methods. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Consecutive series (select one)? No Type(s) of surgery: Complex surgeries anterior and/or posterior Duration of follow-up: 6 days postoperatively and as outpatient for a few weeks. Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☒ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0.6% (2/317) Incidence of PE: 0.3% (1/317) Incidence of Tx Related Complications: None Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question):	*Conclusions relative to question* This paper provides evidence that:there is a very low incidence of DVT (0.6%) and PE (0.3%) with use of compression stockings and pneumatic boots. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:compression stockings and pneumatic boots are effective in preventing DVT and PE. Additionally, routine postoperative ultrasound is not warranted in patients treated with mechanical prophylaxis.	

		Low incidence of VTE with compression stockings and pneumatic boots. Routine ultrasound not warranted. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Mechanical prophylaxis is effective in preventing VTE. Routine ultrasound not warranted.		
Voth D, Schwarz M, Hahn K, Dei-Anang K, al Butmeh S, Wolf H. Prevention of deep vein thrombosis in neurosurgical patients: a prospective double-blind comparison of two prophylactic regimen. Neurosurg Rev. 1992;15(4):289-294.	Level I Type of evidence: prognostic ~~~~~~~ Level II Type of evidence: therapeutic	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: determine the incidence of DVT and PE comparing use of once daily dosing of low molecular weight heparin (LMWH) with dihydroergotamine (DHE) to twice daily dosing of heparin with DHE as prophylaxis in routine, elective lumbar disc surgery. Type(s) of prophylaxis: LMWH/DHE once daily versus heparin/DHE twice daily Total number of patients: 179 Number of patients in relevant subgroups: LMWH/DHE (87 patients) and heparin/DHE (92 patients)	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒Other: two chemoprophylaxis regimens compared (no control group); lack of power; randomization method not specified; screening only immediately postoperatively **PROGNOSTIC ASSESSMENT** *Work group conclusions*	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Consecutive series (select one)? Yes Type(s) of surgery: lumbar disc surgery-laminectomy for herniated disc Duration of follow-up: not specified Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☒ Other (please specify): I125 fibrinogen Results/subgroup analysis (relevant to question): Incidence of DVT: 4.6% (3/87) with LMWH/DHE and 3.3% (3/92) with heparin/DHE Incidence of PE: Incidence of Tx Related Complications: Excessive intraoperative bleeding in 4/92 (4.3%) of the heparin/DHE patients; Intraoperative blood transfusion 5.8% with LMWH and 4.4% with heparin/DHE	Potential Level (select one): I Downgraded Level (select one): I *Conclusions relative to question* This paper provides evidence that: LMWH/DHE regimen and heparin/DHE both have low incidence of DVT but seem to have some mild bleeding sequelae. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:LMWH/DHE regimen and heparin/DHE reduce the risk of DVT, but can result in bleeding complications.	

		Other: **PROGNOSTIC ASSESSMENT** Author conclusions (relative to question): Low but real incidence of DVT in posterior decompression surgery **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): LMWH with DHE is highly safe and effective.		
Wood KB, Kos PB, Abnet JK, Ista C. Prevention of deep-vein thrombosis after major spinal surgery: a comparison study of external devices. J Spinal Disord. Jun 1997;10(3):209-214.	Level I Type of evidence: prognostic ~~~~~~~ Level II Type of evidence: therapeutic	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: To compare two different types of compressive devices (elastic stockings/foot wraps and elastic stockings/pneumatic compression boots) in the prevention of DVT/PE after complex spinal surgery Type(s) of prophylaxis: elastic stockings+foot wraps (n=75) or elastic stockings+pneumatic boots (n=59) Total number of patients: 134 Number of patients in relevant subgroups: n=75 with foot wraps and n=59 with boots	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☒Other: Randomization method not clearly stated. **PROGNOSTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): I	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to question

		Consecutive series (select one)? Yes Type(s) of surgery: Anterior or posterior thoracic, thoracolumbar or lumbar multilevel decompressions and/or spinal fusions Duration of follow-up: At least about a week, otherwise not specified. All patients received duplex study 5 to 7 days postoperatively. Validated outcome measures used (list): visual analog comfort scale Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 2/136 (1.5%) Incidence of PE: 1/136 (0.7%) Incidence of Tx Related Complications: 36/136 (complained of redness/itching) Other:	*Conclusions relative to question* This paper provides evidence that:mechanical prophylaxis is associated with minimal DVT risk and one form is not superior to the other. **THERAPEUTIC ASSESSMENT** *Work group conclusions* Potential Level (select one): I Downgraded Level (select one): II *Conclusions relative to question* This paper provides evidence that:mechanical prophylaxis is effective in reducing DVT risk after major spine surgery, and one form is not superior to the other.	

		PROGNOSTIC ASSESSMENT Author conclusions (relative to question): The rate of DVT after major spinal surgery is low with mechanical prophylaxis. **THERAPEUTIC ASSESSMENT** Author conclusions (relative to question): Mechanical prophylaxis is effective in reducing DVT risk after major spinal surgery.		

CHEMOPROPHYLAXIS PROTOCOL

- **When indicated, what is the ideal time to begin chemoprophylaxis in relation to spinal surgery?**
- **When indicated, how long should chemoprophylaxis be continued following spinal surgery?**
- **In patients who are being treated with chemical anticoagulants for a non-spine related disorder (eg, valve replacement), what is the ideal "bridge" therapy between stopping and starting the usual agent before and after surgery?**

Article (Alpha by Author)	Level (I-V) Type of evidence	Description of study	Conclusion	Explanation of failure to meet guideline inclusion criteria *(when applicable)*
Gerlach R, Raabe A, Beck J, Woszczyk A, Seifert V. Postoperative nadroparin administration for prophylaxis of thromboembolic events is not associated with an increased risk of hemorrhage	Level IV Type of evidence: therapeutic	☐Prospective ☒Retrospective -- (check one) Study design (select one): case series Stated objective of study: Evaluate the incidence of clinically significant hematoma after use of anticoagulation Type(s) of prophylaxis: Nadroparin 0.3ml within 24 hours of surgery continued through hospitalization with compression stockings; hypercoagulable and/or valve patients	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☒Nonrandomized ☒Nonmasked reviewers ☒Nonmasked patients ☒No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available

after spinal surgery. Eur Spine J. Feb 2004;13(1):9-13.		received 0.3-0.6ml every 12 hours; those on anticoagulants received 0.6ml every 12 hours with medication stopped 12 hours prior to surgery and begun 12 hours after surgery. 0.3ml = 2850 IU Total number of patients: 1954 Number of patients in relevant subgroups: cervical surgery 503, thoracic 152, lumbar 1299 Consecutive series (select one)? Yes Type(s) of surgery: Any spinal surgery in any region Duration of follow-up: Duration of hospitalization Validated outcome measures used (list): Nonvalidated outcome measures used (list): Neurological exam Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography	☐Other: *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:Nadroparin 0.3ml may be administered within 24 hours of surgery and continued for the duration of hospitalization. Nadroparin 0.6ml can be used for those patients on anticoagulants every 12 hours with medication stopped 12 hours prior to surgery and resumed 12 hours after surgery.	☐Not relevant to questions

		☒ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0.05% (1/1954) Incidence of PE: 0% Incidence of Tx Related Complications: 8/1954 (0.4%); total hematomas 13 (5 prior to nadroparin) Other: Author conclusions (relative to question): Early nadroparin is safe and does not appear to increase hematoma risk.		
Gruber UF, Rem J, Meisner C, Gratzl O. Prevention of thromboembolic complications with miniheparin-dihydroergotamine in patients undergoing lumbar disc operations. Eur Arch Psychiatry Neurol Sci. 1984;234(3):157-	Level IV Type of evidence: therapeutic Although designed as an RCT, the level of evidence reflects the review of case series level data	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: Evaluate the incidence of bleeding complications using miniheparin starting preoperatively compared to none in a control group Type(s) of prophylaxis: heparin DHE 2500 Total number of patients: 50 Number of patients in relevant subgroups: heparin DHE n=25 and placebo n=25	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☐Nonmasked patients ☒No validated outcome measures used ☒Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐Other:	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to questions

161.	used to address questions related to chemoprophylaxis protocol.	Consecutive series (select one)? Yes Type(s) of surgery: lumbar discectomy Duration of follow-up: until discharge or up to 7 days postoperatively Validated outcome measures used (list): intraoperative bleeding by volume Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☒ Venography ☒ Other (please specify): I125 fibrinogen; V/Q scan or pulmonary angiogram. Results/subgroup analysis (relevant to question): Incidence of DVT: 4% (1/25) with heparin and 0% (0/25) without Incidence of PE: 0 Incidence of Tx Related Complications: 24% (6/25) with heparin and 28% (7/25) without Other:	*Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:heparin DHE may be started preoperatively and continued at 12 hour intervals throughout hospitalization to reduce VTE risk without an increased risk of bleeding complications.	

		Author conclusions (relative to question): Pre- and postoperative heparinization at 2500u twice daily with DHE does not increase bleeding.		
Nelson LD, Jr., Montgomery SP, Dameron TB, Jr., Nelson RB. Deep vein thrombosis in lumbar spinal fusion: a prospective study of antiembolic and pneumatic compression stockings. J South Orthop Assoc. Fall 1996;5(3):181-184.	Level IV Type of evidence: therapeutic Although designed as an RCT, the level of evidence reflects the review of case series level data used to address questions related to chemoprophylaxis protocol.	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: To determine the difference in VTE in patients with elastic stockings compared with stockings and pneumatic compression boots Type(s) of prophylaxis: elastic stockings and ASA 600 mg twice daily postoperatively with or without pneumatic compression boots Total number of patients: 117 Number of patients in relevant subgroups: 60 with stockings and ASA (600 mg twice daily) and 57 with stockings, ASA and boots Consecutive series (select one)? Yes Type(s) of surgery: posterior lumbar decompression with fusion and fixation Duration of follow-up: 2-6 days	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐Other: *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:postoperatively administered ASA (600 mg) may be used in combination with elastic stockings to reduce the risk of DVT/PE.	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to questions

		postoperatively Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0 Incidence of PE: 0 Incidence of Tx Related Complications: None Other: Author conclusions (relative to question): The use of elastic stockings and ASA 600 mg twice daily is satisfactory for DVT prophylaxis		
Rokito SE, Schwartz MC,	Level IV	☒Prospective ☐Retrospective -- (check one)	*Critique of Methodology/ Justification for Downgrading*	*Justification (check all*

Neuwirth MG. Deep vein thrombosis after major reconstructive spinal surgery. Spine. Apr 1 1996;21(7):853-858; discussion 859.	Type of evidence: therapeutic Although designed as an RCT, the level of evidence reflects the review of case series level data used to address questions related to chemoprophylaxis protocol.	Study design (select one): RCT Stated objective of study: To evaluate the incidence of DVT after elective major adult spinal surgery in order to identify the optimal mode of prophylaxis Type(s) of prophylaxis: RCT: elastic stockings v. elastic stockings and pneumatic compression boots v. elastic stockings and Coumadin; Observational: elastic compression stockings v. elastic compression stockings and pneumatic boots Total number of patients: 110 RCT, 219 Observation (n=329) total Number of patients in relevant subgroups: Group 1 (42 patients) received bilateral thigh-high thrombosis embolic deterrent (TED) compression stockings. Group 2 (33 patients) received TED stockings and thigh-length cuffs that provided sequential pneumatic compression to the calf and thigh. Group 3 (35 patients) received TED stockings and low-dose Coumadin. The 219 patients not randomized received either TED stockings alone or TED stockings and pneumatic compression boots for DVT prophylaxis.	*(Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐Other: *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* *This paper provides evidence that:*Coumadin (10mg) administered prior to surgery and continued thereafter to keep INR at 1.3-1.5 does not reduce DVT risks compared to pneumatic compression boots and/or elastic stockings alone, and is associated with a 5.7% incidence of hemorrhage. Pneumatic compression stockings with TEDS and/or TEDS alone reduce the risk of DVT without bleeding complications encountered with Coumadin.	*that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to questions

		Consecutive series (select one)? Yes Type(s) of surgery: Anterior and/or posterior spinal fusions and/or decompression Duration of follow-up: 5-7 days for ultrasound and 1 year clinically Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☒ Ultrasound ☐ Venography ☐ Other (please specify): Results/subgroup analysis (relevant to question): Incidence of DVT: 0.3% overall (1/329), 0% in RCT Incidence of PE: 0 Incidence of Tx Related Complications: 5.7% with Coumadin but 0% without Other:		

		Author conclusions (relative to question): Addition of Coumadin to prophylaxis for elective spine surgery appeared no better than TEDs alone.		
Voth D, Schwarz M, Hahn K, Dei-Anang K, al Butmeh S, Wolf H. Prevention of deep vein thrombosis in neurosurgical patients: a prospective double-blind comparison of two prophylactic regimen. Neurosurg Rev. 1992;15(4):289-294.	Level IV Type of evidence: therapeutic Although designed as an RCT, the level of evidence reflects the review of case series level data used to address questions related to chemoprophylaxis protocol.	☒Prospective ☐Retrospective -- (check one) Study design (select one): RCT Stated objective of study: determine the incidence of DVT and PE comparing use of once daily dosing of low molecular weight heparin (LMWH) with dihydroergotamine (DHE) to twice daily dosing of heparin with DHE as prophylaxis in routine, elective lumbar disc surgery. Type(s) of prophylaxis: LMWH/DHE 32mg/0.5mg once daily + placebo versus heparin/DHE 5000IU/0.5mg every 12 hours; timing was within 2 hours of surgery and for 7 days after. Total number of patients: 179 Number of patients in relevant subgroups: LMWH/DHE=87 Heparin/DHE=92 Consecutive series (select one)? Yes Type(s) of surgery: Lumbar disc surgery	*Critique of Methodology/ Justification for Downgrading (Check all that apply):* ☐Nonconsecutive patients ☐Nonrandomized ☐Nonmasked reviewers ☐Nonmasked patients ☐No validated outcome measures used ☐Small sample size ☐<80% follow-up ☐Lacked subgroup analysis ☐Diagnostic method(s) not detailed ☐Other: *Work group conclusions* Potential Level (select one): IV Downgraded Level (select one): IV *Conclusions relative to question* This paper provides evidence that:LMWH/DHE regimen and heparin/DHE both have low incidence of DVT but seem to have some mild bleeding sequelae. LMWH with DHE may be administered for lumbar disc	*Justification (check all that apply):* ☐Level V (expert consensus) ☐Level IV in presence of higher quality studies ☐Subgroup analysis data not available ☐Not relevant to questions

		Duration of follow-up: 8 days Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☒ Other (please specify): I125 fibrinogen Results/subgroup analysis (relevant to question): Incidence of DVT: 4.6% (3/87) with LMWH/DHE and 3.3% (3/92) with heparin/DHE Incidence of PE: Incidence of Tx Related Complications: Excessive bleeding in 4/92 (4.3%); Intraoperative blood transfusion 5.8% with LMWH and 4.4% with heparin Other: Author conclusions (relative to question): LMWH with DHE, as administered in this	surgery two hours preoperatively and maintained for seven days postoperatively to minimize the incidence of VTE.	

		Duration of follow-up: 8 days Validated outcome measures used (list): Nonvalidated outcome measures used (list): Diagnosis of DVT/PE made by (check all that apply): ☒ Clinical exam ☐ Ultrasound ☒ Venography ☒ Other (please specify): I125 fibrinogen Results/subgroup analysis (relevant to question): Incidence of DVT: 4.6% (3/87) with LMWH/DHE and 3.3% (3/92) with heparin/DHE Incidence of PE: Incidence of Tx Related Complications: Excessive bleeding in 4/92 (4.3%); Intraoperative blood transfusion 5.8% with LMWH and 4.4% with heparin Other: Author conclusions (relative to question): LMWH with DHE, as administered in this	surgery two hours preoperatively and maintained for seven days postoperatively to minimize the incidence of VTE.	

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