THE SULLIVAN GROUP

TSG NEWSLETTER

SAVING LIVES - REDUCING RISK

From The Editor

In this issue TSG addresses the relatively new and increasing risk of spontaneous bleeding from anticoagulant medication. We recently completed two computer based courses on this important subject and our thanks to Tom Syzek, MD, FACEP, for providing an overview of the courses and the patient safety and medicolegal risks involved. Tom is a veteran emergency physician and senior physician with Premier Health Care Services in Dayton, Ohio. He is also the Director of Risk Management for Premier Health Care Services and is an active member of the ACEP Medical Legal Committee. Tom has been a medical advisor with TSG for over 5 years.

In our last issue we "got out the crystal ball" and addressed current and future trends in emergency medicine, patient safety, and risk. We received a lot of positive feedback from interested readers and there were multiple requests for a live presentation on the subject. Therefore, TSG ventured into new territory and presented a live symposium on the subject. To view a recording of this presentation go to "News & Events / TSG Presentations" at www.thesullivangroup.com and click on Emergency Medicine Malpractice Trends Symposium. We are very interested in your feedback on the project.

Finally, we have included an update of TSG activities and risk and safety tools. For example, TSG has been approved to provide risk and safety computer based CME at no cost to physicians in the armed services deployed overseas. Read more about this in the TSG Update section of the newsletter ■

In This Issue...

Walking The Tightrope – Patients On Anticoagulant Medications

One of the greatest advances in medicine is the discovery of medications that inhibit the clotting of blood. As the secrets of coagulation have been unlocked, new drugs have been developed to interfere with clotting through a host of complex mechanisms. Thanks to pharmaceutical research and development we now have at our disposal a brilliant category of medications that help millions of people worldwide by preventing disease, improving longevity, and saving lives. Most practitioners are very familiar with the handful of "blood thinners" in common use today including aspirin, heparins, warfarin (Coumadin), and clopidogrel (Plavix). There are dozens more products for oral and parenteral administration.

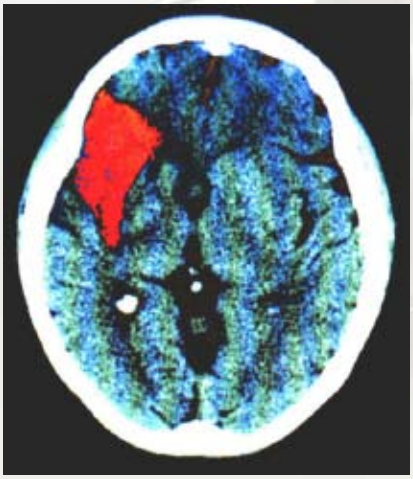
In the past few decades the indications for anticoagulant therapy have multiplied. They are used as prevention and treatment in many conditions where clotting is undesirable, including deep vein thrombosis, pulmonary embolism, coronary disease, valvular heart disease, atrial fibrillation, TIA, stroke, hypercoagulable states, vascular diseases, and more. Yet, despite their indisputable value they remain under used in some conditions such as atrial fibrillation and TIA.

Anticoagulant medications are prescribed so often it would be a rare day in the office, emergency department, or hospital for a practitioner not to encounter a patient taking one or more of them. Along with the beneficial effects, clinicians are also encountering serious complications and even deaths related to anticoagulant use.

With Power Comes Responsibility

As with every new therapy, the advent of anticoagulants is accompanied by a unique set of risks, complications, and medical-legal land mines. Practitioners are now armed with an array of powerful weapons against undesired thrombosis, but also bear the responsibility to use these weapons selectively and safely.

Some adverse effects are uncommon, such as heparin-induced thrombocytopenia (HIT), thrombotic thrombocytopenic purpura (TTP) associated with clopidogrel, and "purple toes syndrome" from warfarin. Because these side effects are infrequent, practitioners may be only vaguely familiar with them. However, you can bet that internet-savvy patients taking these medications will know about these adverse effects and a lot more. It is a fact that there are many attorney websites advertising their services to patients injured by heparin, clopidogrel, and warfarin. An entire industry of anticoagulant-related litigation is flourishing.



We have all seen the patient on anticoagulant medication with a minor nosebleed that required nothing more than cautery or packing. Similarly, lacerations bleed longer and contusions bruise more extensively in anticoagulated patients. Prolonged bleeding in visible locations such as the nose and skin is, for the most part, easily recognizable and treatable with local measures. It is not likely that major medical errors and serious adverse outcomes result from nosebleeds and superficial lacerations.

From the standpoint of risk and safety, the major issue related to anticoagulant class of medications, and warfarin in particular, is the occurrence of hemorrhage not visible to the naked eye. Hidden from view, detection of hemorrhage can be delayed or missed altogether, resulting in disastrous outcomes. Hemorrhages have been reported in nearly every bodily location including Intracranial, intraocular, retropharyngeal, perispinal, pericardial, intra-abdominal, renal, retroperitoneal, and intramuscular. Even if a hemorrhagic complication is immediately diagnosed and treated, the potential for disability and death due to blood loss and organ failure remains a very real possibility.

Spotlight On Warfarin

Knowledge of the pharmacology, indications, monitoring, drug interactions, and complications of anticoagulant drugs is an essential tool to ensure maximal patient safety while avoiding the medical-legal vulnerabilities associated with their use. With no intent to minimize the dangers of other medications, it is worthwhile to spotlight warfarin since our experience at TSG shows that adverse events related to warfarin are common, high-risk, and a source of litigation. We have concluded that the topic of warfarin-related complications is so important, that we are

releasing two new courses on "warfarin complications" in 2009!

INR Values: Not Where You Want Them To Be

Faced with an ill or injured patient on warfarin, every practitioner wonders when to order an INR. At least one study adds punch to the argument in favor of ordering INR testing liberally in the ED. Results revealed

that 72% of the 782 ED patients taking warfarin had values outside the therapeutic range of 2.0 to 3.0. About 43% were too low and 29% were too high. Many of these patients suffered complications as a result of their non-therapeutic INR, including DVT, stroke, or intracranial hemorrhage.

The message is simple – measure the INR. Practitioners order "routine" blood work including INR for far less compelling indications, even for patients who are not taking warfarin! Ask yourself if it makes any sense NOT to order an INR for any ill or injured patient on warfarin.

Once the INR has been obtained, the results should be routinely documented. The adequacy of warfarin therapy should be addressed by clinicians in a discussion of the medical decision-making. If the INR is either below or above the therapeutic range, it would be wise to chart the detailed instructions provided to the patient, which should include: a plan for subsequent dosage adjustments, when to obtain the next INR, when to follow up and with whom, and the reasons to seek immediate medical attention. If the INR is elevated above the therapeutic ranges, use the latest guidelines from the American College of Chest Physicians to direct your treatment.

Not Enough Warfarin Can Be A Problem?

Our review of claims shows that malpractice litigation related to warfarin therapy generally falls into two categories. The first category of suits includes cases where the patient had a medical condition necessitating anticoagulation, but either received subtherapeutic doses of warfarin or was not prescribed warfarin at all. In this group of

patients a complication occurs that warfarin was meant to prevent.

Examples of these bad outcomes related to "under-anticoagulation" include: a stroke in a patient with atrial fibrillation, a pulmonary embolism in a patient with DVT of the leg, and a systemic embolization in a patient with a mechanical heart valve.

Consider the case of a 55 year old man who presents with symptoms of a TIA, including right arm weakness and difficulty talking. His history included hypertension controlled with a beta blocker. The symptoms lasted 45 minutes and his neurological exam was normal. Blood work and head CT were normal. His EKG showed atrial fibrillation and he was known to be in sinus rhythm nine months prior. Ten days later, while awaiting his outpatient workup for TIA, he suffered a debilitating stroke and did not reach the hospital in time for thrombolytic therapy. He filed suit against the practitioner for failing to initiate warfarin therapy for his atrial fibrillation, arguing that this failure directly caused his stroke.

Typical allegations found in this category of "under-anticoagulation" include:

- Failure to recognize the indications for warfarin therapy
- Failure to prescribe warfarin for an indicated condition
- Failure to prescribe an adequate dose of warfarin
- Failure to maintain the patient on warfarin for an adequate duration
- Failure to monitor the INR in a patient taking warfarin
- Failure to recognize and/or treat complications of "under-anticoagulation"

Hemorrhagic Complications

At the other end of the spectrum are cases involving hemorrhagic complications of warfarin. Way back in 1950 the authors of a book on thromboembolism and anticoagulation declared, "when bleeding occurred from the clinical use of Dicumarol (a drug similar to warfarin) the fault rested with the physician who administered the drug."

It should be made clear that not all bleeding complications related to warfarin therapy are the result of negligence. However, many are preventable and more than a few cases have resulted in litigation. In the absence of hard statistics, our experience at

The Sullivan Group shows that litigation related to hemorrhagic complications is much more common than suits related to "under-anticoagulation."

Warfarin And Intracranial Hemorrhage

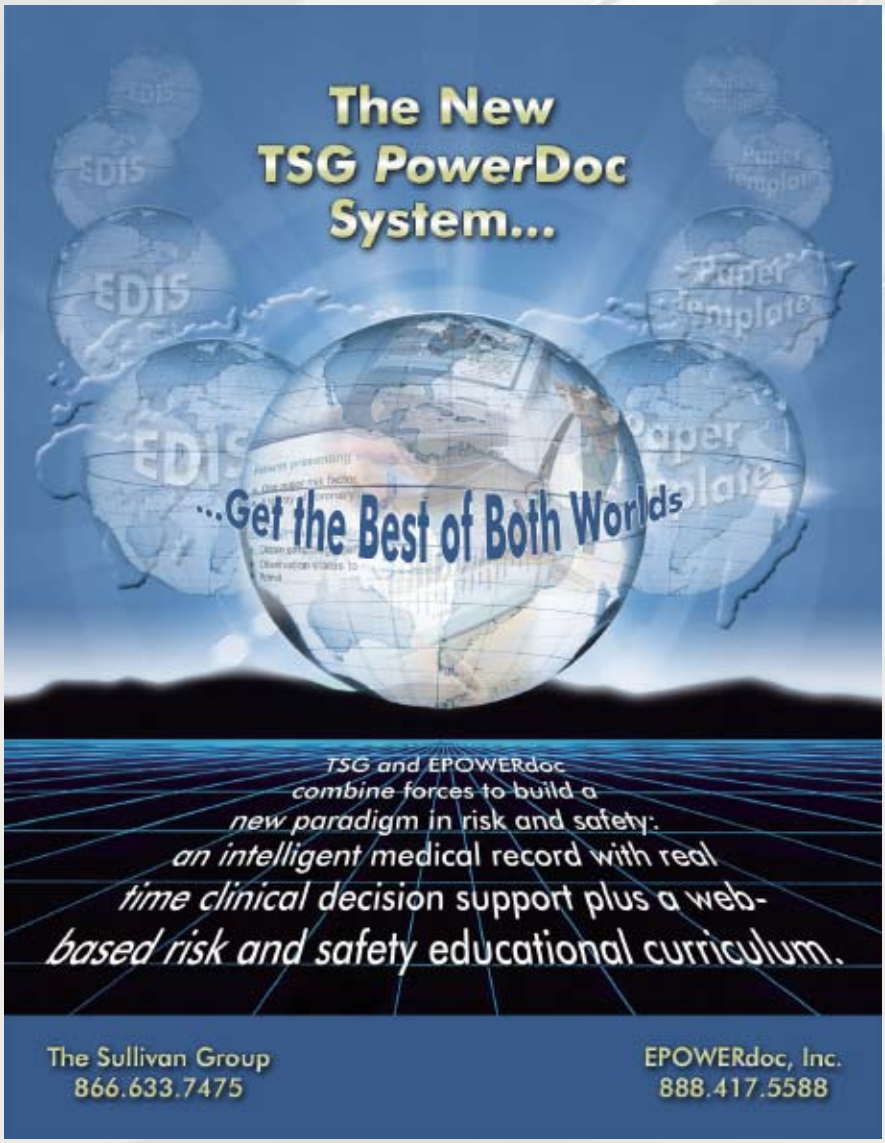
Of all the anatomical locations associated with warfarin-related bleeding, perhaps none is as ominous as intracranial hemorrhage (ICH). At the top of the list as the most serious and lethal hemorrhagic complication of warfarin, it deserves special mention. Studies have found that warfarin anticoagulation increases the risk of intracranial hemorrhage 7 to 10 fold.

A typical case is the 77 year old woman taking warfarin for atrial fibrillation, who is brought to the ED with a scalp laceration. There was no witnessed fall and she reported no loss of consciousness. Her GCS was 15 and the neurological exam was "without focal deficit." The laceration was sutured and she was discharged. The next day her daughter noticed a declining mental status and brought her back to the ED. Her INR was elevated to 5.2 and a repeat head CT showed a large subdural hematoma. She died of complications after neurosurgery. The family successfully sued the first emergency physician for failure to measure and treat an elevated INR and for failure to perform a head CT, which allegedly would have diagnosed the subdural hematoma.

Anticoagulation And The Spontaneous Spinal Epidural Bleed

Another potential disaster related to warfarin and other anticoagulant medications is the spontaneous spinal epidural bleed. These cases often present as an acute onset of back pain without an apparent mechanism of injury. The practitioner simply does not consider this clinical entity in the differential diagnosis. Patients may be discharged with a diagnosis of vertebral osteoarthritis or back strain. If the bleeding continues patients often develop severe and permanent neurologic disabilities. TSG has seen an increasing number of these cases over the last few years. The key

Introducing A New & Safe Way To Practice



is to consider the risk of these medications and include the spinal epidural bleed in the differential diagnosis in appropriate cases.

Don't Forget The Basics: The Neurological Exam

Intracranial hemorrhages account for 90% of the fatalities and nearly all residual disability from warfarin-associated hemorrhage. Surprising as it may seem, the neurologic exam is often minimal or missing from patient charts – even those with neurologic symptoms. Perhaps since the neurologic exam is the last exam documented, it sometimes does not make it onto the medical record. The neurologic exam is the highest yield exam in patients on warfarin. Consider documenting it first in the physical examination. Make it clear that you documented a complete exam. Don't leave any room for interpretation. Statements like "Neuro exam WNL" are not adequate.

We are all aware that head injury, with or without warfarin, can cause intracranial hemorrhage (ICH). What all practitioners may not fully appreciate is the fact that ICH can occur spontaneously, in the absence of any trauma, in patients taking warfarin. It is further distressing to realize that warfarin-related spontaneous intracranial hemorrhages occur even in the face of a therapeutic INR. In any patient on warfarin, the prudent practitioner should maintain a high index of suspicion for bleeding complications.

Risk Factors For Hemorrhage

Several risk factors have been identified which increase the risk of hemorrhage in a given patient. The number one risk factor is the intensity of the warfarin treatment. Put very simply, the higher the INR, the higher the risk for bleeding complications. The risk of intracranial hemorrhage rises substantially when the INR exceeds the 4.0 - 5.0 range. Other medical conditions and patient characteristics associated with an increased risk for bleeding during warfarin therapy include age >65, hypertension, history of previous bleeding episodes, anemia, alcohol abuse, heart disease, stroke, diabetes, renal disease, liver disease, malignancy, and genetic factors.

Some of the allegations related to hemorrhagic complications in patients taking warfarin are listed below. These alleged failures constitute a valuable list of "land mines" encountered by clinicians during their management of patients on warfarin.

- Failure to elicit or document the history that the patient is taking warfarin
- Failure to recognize that drugs, diet, or concomitant illness can potentiate warfarin
- Failure to include hemorrhagic complications in the differential diagnosis
- Failure to realize that trauma, however minor, may cause significant bleeding
- Failure to perform a CT for head trauma
- Failure to inform the patient of potential complications related to warfarin therapy
- Failure to routinely monitor the INR in a patient taking warfarin
- Failure to measure the INR in a warfarin patient presenting with acute illness or injury
- Failure to appropriately treat the patient with an elevated INR or bleeding complications

Due to the propensity for permanent disability and death from either under use of warfarin or its hemorrhag-

ic complications, the monetary awards to successful plaintiffs can be huge. One major physician liability insurer reported that it has paid over $5 million for claims related to warfarin.

Information from another insurer indicated that 75% of warfarin-related litigation involved the specialties of General Practice, Family Practice, and Internal Medicine. Cardiovascular surgeons and cardiologists together made up 20% of the suits. Other specialties were named in a suit less frequently, including OB/GYN. Our experience at TSG indicates that emergency physicians are also targets for claims related to warfarin complications.

Warfarin: On The "A-List"

Warfarin is listed by the Institute for Safe Medication Practices as a "High-Alert Medication," defined as "a drug that bears a heightened risk of causing patient harm when used in error." This dubious distinction seems to be borne out in a retrospective study involving emergency department patients that found warfarin to be the 2nd most common drug responsible for adverse drug events.

The adverse events related to warfarin were coagulopathy and hemorrhage. This study confirms what healthcare providers already know – warfarin is a high risk drug sometimes associated with serious complications and bad outcomes. Any patient on warfarin should be accompanied by an enormous red flag. Warfarin has earned its place on the list of "the most dangerous drugs in the world."

The Warfarin Checklist

Below is a checklist of 7 questions to consider during the evaluation of a patient taking warfarin, particularly in the acute care setting. We recommend that you commit this list to memory or keep it where you can easily refer to it.

- ☑ Has there been a change in diet, medications, or illness that could affect the INR?
- ☑ Does the patient have any head trauma?

- ☑ Should I get an INR level?
- ☑ Does this patient need treatment for a subtherapeutic INR to prevent complications?
- ☑ Does this patient need treatment for an elevated INR to prevent hemorrhagic complications?
- ☑ Is it possible that a hemorrhagic complication exists?
- ☑ Does this patient need immediate treatment for an elevated INR with serious or life-threatening bleeding?

Treat With Caution And Respect

There are many factors that increase the risk of hemorrhage for patients who take warfarin. In a nutshell, it would be wise for clinicians to assume that any new drug, supplement, illness, or dietary change can affect the fickle pharmacokinetics of warfarin. The very antibiotic prescribed to fight infection may cause a warfarin-associated hemorrhage. The official package insert lists 132 drugs that can interact with warfarin to increase the INR and another 44 drugs that can interact to decrease the INR.

Whether in the office, clinic, ED, or hospital, wise practitioners have a low threshold for measuring the INR in patients on warfarin – particularly if there has been any recent pause or change in dosage, neurologic symptoms, trauma, medical illness, new prescriptions, or symptoms of bleeding.

Complications related to warfarin and other anticoagulant drugs are a major patient safety issue and a source of preventable medical error. Recognition of the indications and complications will improve the quality of patient care, while at the same time minimizing the practitioner's exposure to medical-legal risk as well.

That concludes TSG's look at this relatively new and growing patient safety issue. If you are interested in additional information on the subject including several demonstrative cases, TSG will be offering two related courses that will be made available mid-year.

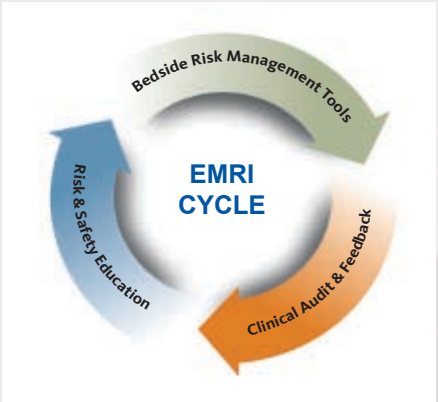
As always we welcome your feedback. Do you have an interesting case in the areas described above? We would love to have you share that experience. Was this overview helpful? We would love to hear from you.

Thanks ■

TSG Update

The TSG mission is the creation of system solutions that improve patient safety, reduce medical errors, and decrease the risk of exposure to medical malpractice claims. The following information contains an overview of our programs and access to a series of presentations and additional information available through our website.

1. **Emergency Medicine Risk Initiative (EMRI).** This is the TSG core program that has been implemented at several of the largest healthcare organizations in the country. The program consistently results in demonstrable improvements in patient safety, error reduction, and a reduction in malpractice frequency. The program is based upon risk reduction strategies utilized in other error prone industries and includes web-based risk and safety education, risk enhanced intelligent medical record tools, and a web-based risk and safety focused performance evaluation. The return on investment for our clients has been substantial. For an overview presentation of EMRI go to "News & Events / TSG Presentations" at www.thesullivangroup.com and click on Emergency Medicine Risk Initiative.



2. **Update: Armed Forces Will Start TSG Courses.** TSG has offered the risk and safety computer based courses with CME at no cost to emergency physicians in the armed services deployed outside of the United States. We are very excited and proud that the uniformed services have accepted our offer and will begin taking courses in the near future.

3. **Update: Resident Risk And Safety Curriculum.** Several emergency medicine residency programs utilize our risk and safety curriculum at no cost. TSG continues to offer the online course libraries free of charge to assist emergency medicine residencies develop risk management curricula. If you are a residency director and have an interest in reviewing the course libraries please call us at any time.

4. **Emergency Medicine Malpractice Trends Symposium.** Dr. Dan Sullivan has just completed a live online symposium addressing current trends in emergency medicine malpractice. To view a recording of this presentation go to "News & Events / TSG Presentations" at www.thesullivangroup.com and click on Emergency Medicine Malpractice Trends Symposium.

5. **TSG *PowerDoc*™**. The majority of emergency departments continue to use paper templates or dictation. The existing paper template systems are fine for billing and coding, but do not adequately address risk and safety or minimize your malpractice exposure. Dictation systems are extremely costly in today's financial environment and do not assist emergency practitioners minimize risk.

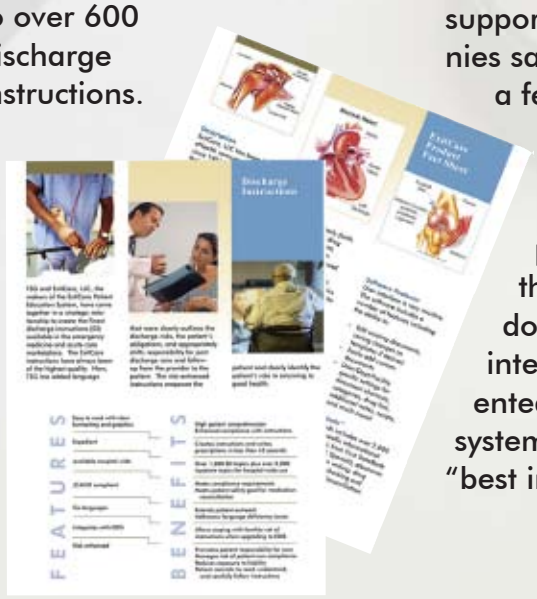
   TSG entered into a strategic relationship with EPOWERdoc and developed the TSG *PowerDoc*™ System. The system provides access to over 200 risk and safety enhanced medical records together with a first of its kind computer application presenting "real time" risk and safety clinical decision support called **TSG*RSQ***™. It is an unprecedented approach that has no equal in emergency medicine.

   To view a presentation of the system, go to "News & Events / TSG Presentations" at www.thesullivangroup.com and click on TSG *PowerDoc*.

6. **Update: Computer Based Training.** TSG has now provided over a quarter million computer based risk and safety courses to over 30,000 practitioners. The TSG library continues to grow and address current and future emergency, urgent care, and acute care risk. If you have an interest in sampling the courses please call us at any time.

7. **Risk And Safety Enhanced ExitCare Discharge Instructions.** Electronic discharge instruction companies have not taken advantage of the huge oppor-

tunity to improve patient safety and minimize risk at the time of patient discharge. TSG has entered into a strategic relationship with ExitCare and has provided risk and safety enhancements to over 600 discharge instructions.



To view a short presentation of this development go to "News & Events / TSG Presentations" at www.thesullivangroup.com and click on Exitcare Discharge Instructions.

8. **Risk And Safety Enhanced Electronic Medical Records.** If you are considering an electronic medical record system be certain that it addresses patient safety and risk reduction through clinical decision support. A lot of companies say they do, but only a few are truly committed to the patient safety mission. TSG has partnered with those few EMR vendors and has fully integrated our patented risk and safety system into their already "best in class" systems.

Call for more information on this critical topic ■

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