WoundStat Superior in Hemostatic Comparison

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SAN DIEGO — WoundStat, a hemostatic agent approved in August 2007, is superior to other combat hemostatic agents used for combat and civilian trauma, results from a swine study demonstrated.

The product, marketed by TraumaCure Inc., consists of a pure granular smectite composite. In the study, it produced hemostasis in the face of high-pressure arterial bleeding within 3 minutes. WoundStat is currently used as a life-saving tool by the U.S. military in Afghanistan.

“The study protocol was to hold for 3 minutes, but in subsequent studies and observations, 2 minutes was more than sufficient for WoundStat to stop the hemorrhage,” Robert F. Diegelmann, Ph.D., said at the annual meeting of the Wound Healing Society. It also would be simple for the victim or medic to apply.

Dr. Diegelmann, professor of biochemistry and molecular biology, anatomy, and emergency medicine at Virginia Commonwealth University, Richmond, led the research team that developed WoundStat at the university’s reanimation engineering shock center.

He and his associates compared the performance of WoundStat with Z-Medica Corp’s QuikClot zeolite granules and QuikClot zeolite Advance Clotting Sponge, HemCon Medical Technologies Inc.’s chitosan bandage, and the U.S. Army field gauze bandage in a lethal vascular injury model developed by the Army (J. Trauma 2007;63:276-84). The protocol involved creating a 6-mm arteriotomy in a vessel of 25-male swine. After 45 seconds of hemorrhage, five animals each were randomized to be treated with the Army field bandage (control group), QuikClot zeolite granules, the QuikClot zeolite Advance Clotting Sponge, the HemCon chitosan bandage, or WoundStat.

The application of WoundStat, a pre-

IMPORTANT SAFETY INFORMATION

Risk of Serious Infections
Infections, including serious infections leading to hospitalization or death, have been observed in patients treated with ENBREL. Infections have included bacterial sepsis and tuberculosis. Patients should be educated about the symptoms of infection and closely monitored for signs and symptoms of infection during and after treatment with ENBREL. Patients who develop an infection should be evaluated for appropriate antimicrobial treatment and, in patients who develop a serious infection, ENBREL should be discontinued.

Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation) has been observed in patients receiving TNF-blocking agents, including ENBREL. Tuberculosis may be due to reactivation of latent tuberculosis infection or to new infection. Data from clinical trials and preclinical studies suggest that the risk of reactivation of latent tuberculosis infection is lower with ENBREL than with TNF-blocking monoclonal antibodies. Nonetheless, postmarketing cases of tuberculosis reactivation have been reported for TNF blockers, including ENBREL.

Patients should be evaluated for tuberculosis risk factors and be tested for latent tuberculosis infection prior to initiating ENBREL and during treatment. Treatment of latent tuberculosis infection should be initiated prior to therapy with ENBREL. Treatment of latent tuberculosis in patients with a reactive tuberculin test reduces the risk of tuberculosis reactivation in patients receiving TNF blockers. Some patients who tested negative for latent tuberculosis prior to receiving ENBREL have developed active tuberculosis. Physicians should monitor patients receiving ENBREL for signs and symptoms of active tuberculosis, including patients who tested negative for latent tuberculosis infection.

Many of these serious infections occurred in patients predisposed to infection because of concomitant immunosuppressive therapy and/or their underlying disease. Do not start ENBREL in the presence of sepsis, active infections (including chronic or localized), or allergy to ENBREL or its components. Use caution in patients predisposed to infection, such as those with advanced or poorly controlled diabetes.

Neutrophil Events
TNF inhibitors, including ENBREL, have been associated with rare cases of new onset or exacerbation of CNS demyelinating disorders (some presenting with mental status changes and some associated with permanent disability). Transverse myelitis, optic neuritis, multiple sclerosis, and cases of new onset or exacerbation of seizure disorders have been observed in association with ENBREL therapy. The causal relationship to ENBREL therapy remains unclear. Exercise caution when considering ENBREL for patients with these disorders.

Hematologic Events
Rare cases of pancytopenia, including aplastic anemia, some fatal, have been reported. The causal relationship to ENBREL therapy is unclear. Exercise caution in patients who have a previous history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs or symptoms of blood dyscrasias or infection. Consider discontinuing ENBREL if significant hematologic abnormalities are confirmed.

Malignancies
In clinical trials of all TNF inhibitors, more cases of lymphoma were seen compared to control patients. The risk of lymphoma may be up several-fold higher in RA and psoriasis patients; the role of TNF inhibitors in the development of malignancies is unknown. In clinical trials, the incidence of malignancies other than lymphoma has not increased with exposure to ENBREL and is similar to what would be expected in the general population.

Hepatitis B Reactivation
TNF inhibitors, including ENBREL, have been associated with reactivation of hepatitis B virus (HBV) in chronic carriers of this virus. The majority of these reports occurred in patients on concomitant immunosuppressive agents, which may also contribute to HBV reactivation. Prescribers should exercise caution in prescribing TNF blockers for patients identified as carriers of HBV.

Adverse Events
The most commonly reported adverse events in RA clinical trials were injection site reaction, infection, and headache. In clinical trials of all other adult indications, adverse events were similar to those reported in RA clinical trials.

Please see brief summary of Prescribing Information on adjacent pages.
mixed composite available in 5-ounce packages, also involved the application of 200 mm Hg pressure over the product in the wound for 3 minutes.

In all cases, fluid resuscitation began at the time each product was applied, with 500 mL of Hextend, followed by lactated Ringer’s solution at 100 mL/kg/h to maintain a mean arterial blood pressure of 65 mm Hg. The study’s primary end points were survival, survival time, posttreatment blood loss, and amount of resuscitation fluid required. All swine in the WoundStat group survived to 180 minutes and required only a single application. Dr. Diegelmann said at the meeting, held in conjunction with a symposium on advanced wound care.

He reported that survival and survival times for animals in the WoundStat group were significantly greater, compared with those in all other groups. In addition, posttreatment blood loss and lost-resuscitation fluid volume were significantly less for animals in the WoundStat group, compared with all other groups. Dr. Diegelmann disclosed that he is a paid consultant for TraumaCure Inc.™

The interaction of whole blood and WoundStat resulted in the aggregated red cells and formation of fibrin matrix seen in this scanning electron micrograph (3,300X) of a sample fixed during a span of 1 minute after the addition of the blood.