Blunt Suture Needles Advocated as Safe, Effective

American College of Surgeons issues statement in effort to improve safety of physicians and patients.

BY DOUG BRUNK
San Diego Bureau

A new statement from the American College of Surgeons endorses the universal adoption of blunt suture needles for all potential applications in the operating room.

"There are surgeons who don't even know that blunt sutures exist for fascial and muscle closure," said Lena M. Napolitano, M.D., a surgeon who chairs the ACS Committee on Perioperative Care, which assembled the statement. "What we are proposing is that this should become the standard. Rather than using sharp needles to close the fascia and muscle, we should convert to using blunt suture needles because that's the safest for our health care workers in the OR."

Released in August, the statement (see www.facs.org) comes on the heels of mounting research that demonstrates how the OR lags behind other areas of the hospital in implementing safety-engineered devices required by the Needlestick Safety and Prevention Act of 2000. According to a study of percutaneous injuries that occurred at various hospitals in the United States between 1993 and 2002, a 38.1% reduction in injuries was seen in patient rooms, compared with only a 5.7% drop in the OR.

The study, conducted by the International Healthcare Worker Safety Center at the University of Virginia Health System, Charlottesville, also found that while injury rates from hollow-bore needles declined by 32.8% between 1993 and 2002, injury rates from suture needles increased by 26.8% over that same period.

"There has been a sea change of progress in [needlestick safety], but most of it has been focused on hollow-bore needles such as syringes, blood-drawing devices, and IV equipment," said Janine C. Jagger, Ph.D., professor of research and internal medicine at the University of Virginia, Charlottesville, and director of the International Healthcare Worker Safety Center. "The Needlestick Safety and Prevention Act of 2000 requires employers to purchase devices with needlestick prevention features on them. But it seems as though the operating room is the last frontier."

'There are surgeons who don't even know that blunt sutures exist for fascial and muscle closure.' These needles should become the standard.

Dr. Jagger called the new ACS statement on blunt suture needles "an extremely important step" in improving safety for surgeons, health care workers, and patients. "What we do in America has a huge impact elsewhere in the world," she said, noting that sharp suture needles are the No. 2 cause of needlestick injuries in the hospital setting, right behind syringes. "There are countries that use American standards to set their own standards. Surgical societies around the world will be influenced by this."

Blunt suture needles have been on the market for more than 10 years. They can be used for suturing most internal tissues, such as muscle, fascia, and fat, but not to suture vascular tissue or skin.

In 2004 they accounted for only about 3% of the suture needle market for general closure. Ethicon Inc. and U.S. Surgical market the needles, which currently cost about 10% more than sharp suture needles.

"When these needles were first developed, there was not much uptake by surgeons," said Dr. Napolitano, who is also professor of surgery and associate chair for critical care at the University of Michigan, Ann Arbor. "We are a little bit behind [in using them]. I don't think it's a matter of surgeons not embracing [these needles]. I just don't think people know about them."

She added that switching from sharp suture needles to blunt suture needles requires little change in technique. "Until you use them a couple of times, you do feel a little more resistance to tissue penetration, as you would expect. But you get used to that very quickly," she said.

Blunt suture needles may not yet be widely accepted in the United States, but they are in Japan, thanks largely to Dr. Jagger, who over the past few years helped that country's surgeons establish a national surveillance program for needlestick injuries and promoted the use of blunt suture needles in the process.

"It was a very simple thing for the Japanese to undergo this transition," she said, adding that the surgeons there presumed blunt suture needles were part of routine clinical practice in the United States until she informed them otherwise. "There was no resistance. They only found further advantages when they started using them. I've never seen a device transition go so quickly and so smoothly."

Dr. Jagger said she finds it ironic that surgeons in the United States have not widely adopted them, "especially since they're the simplest and cheapest of all the safety devices. When surgeons start using them, they don't have any objections. The hard part is just to get them to try."

Dr. Napolitano called the adoption of blunt suture needles in the OR a matter of safety for everyone. "If you've ever seen any health care worker acquire hepatitis or HIV, these are chronic, lifelong diseases, so any prevention we can do is well worth it," she said. ■

Signs May Precede Ovarian Ca Diagnosis by Months

A study of California women with ovarian cancer showed that the patients had distinguishable symptoms at least 6 months before diagnosis, according to Lloyd H. Smith, M.D., Ph.D., chair of the department of ob.gyn. at the University of California, Davis, and his colleagues.

The researchers found that women with ovarian cancer more frequently reported abdominal pain and received abdominal imaging in the 7-9 months before their diagnosis, compared with women who had no cancer and those with early-stage breast cancer (Cancer [online]2005;DOI:10.10002/cncr.21310).

And some patients may have their diagnosis delayed by 4 months or more because physicians order abdominal imaging or perform gastrointestinal procedures before ordering pelvic imaging or CA 125 screening, which are more likely to diagnose ovarian cancer, the researchers reported.

The population-based, retrospective case-control study compared case reports from 1,985 women, aged 68 years or older with a diagnosis of ovarian cancer, with two control groups: 10,941 women with early-stage breast cancer and 6,024 randomly selected age-matched women with no diagnosis of cancer. Researchers used information from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program and from Medicare Part B claims from women in California.

In the 1-3 months before diagnosis of ovarian cancer, 31% of women reported abdominal pain, 17% reported abdominal swelling, and 8% reported gastrointestinal symptoms.

Abdominal imaging and pelvic imaging/CA 125 screens were used frequently (70% and 54%, respectively) to investigate symptoms within 3 months prior to diagnosis of ovarian cancer. In the 4-36 months before their diagnosis, 61% of women with symptoms had abdominal imaging and 25% received pelvic imaging/CA 125 screening.

Although pelvic imaging and CA 125 screens are not recommended in asymptomatic patients, they could be "reasonable options for women who have target symptoms that are not explained by routine medical evaluation," the researchers reported.

—Mary Ellen Schneider

Valacyclovir Proves Safe For HSV-2 Suppressive Therapy of Up to 20 Months

BY SHARON WORCESTER
Southeast Bureau

Charleston, S.C. — Once-daily treatment with valacyclovir for the suppression of genital herpes caused by herpes simplex virus type-2 was well-tolerated for up to 20 months in a recent study.

Previously, data were available only for up to 12 months of daily valacyclovir use, Zane A. Brown, M.D., of the University of Washington, Seattle, and his colleagues reported in a poster at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology.

For the current study, which was supported by GlaxoSmithKline Inc., 1,484 serodiscordant, heterosexual, monogamous couples were enrolled, and the seropositive partner was randomized to receive either placebo or 500 mg/day of valacyclovir for 8 months.

The results of this double-blind phase, which were previously reported by the investigators, showed that the treatment significantly reduced the risk of genital herpes transmission.

Following the double-blind phase, 1,018 of the 1,484 participants treated in the double-blind phase entered an open-label suppression phase of the study, which provided 12 months of suppressive therapy with 500 mg/day of valacyclovir. Patients in this phase were evaluated every three months for laboratory values and adverse events.

More than 85% of participants who completed the entire 20 months of treatment were at least 80% compliant with the study medication.

During the double-blind and open label phases, the nature and incidence of adverse events were similar in the 519 participants originally assigned to receive valacyclovir (treatment group) and the 499 originally assigned to receive placebo.

Common adverse events included headache, nasopharyngitis, and upper respiratory tract infection.

Serious adverse events were reported infrequently and were similar in frequency in the treatment group (5% incidence rate) and the placebo group (3% incidence rate). Only one serious adverse event (gastritis in one patient) during the entire 20-month study was considered by the investigators to be possibly attributable to valacyclovir, and it occurred during the open-label portion of the study.

Adverse events leading to treatment discontinuation occurred in fewer than 1% of those in the treatment group, and in 1% of those in the placebo group; clinically significant laboratory abnormalities occurred in 6% of patients in both groups.

No deaths occurred during the study periods, the investigators reported. ■

Pages 34a—34d