Palm Springs, Calif. — Pain scores declined by half and opioid use significantly declined in a small number of patients treated with spinal cord stimulation for chronic visceral pelvic pain at the Cleveland Clinic Foundation, said Nagy Mekhail, M.D., chairman of pain management, and his associate Leonardo Kapural, M.D., conducted a small clinical study of spinal cord stimulation for pelvic pain based on recent studies implicating dorsal column pathways in the transmission of visceral pelvic pain.

Six patients were enrolled in the study Dr. Mekhail presented at the annual meeting of the American Academy of Pain Medicine.

All had long-standing histories of chronic pelvic pain of a mean duration of nearly 15 years. All had pelvic adhesions and had undergone multiple surgical explorations for endometriosis and other diagnoses. Their clinical diagnoses included chronic pelvic inflammatory disease, adenomyosis, endometriosis, and mean opioid use was reduced from 22.5 mg morphine equivalent per day to 6.6 mg per day.

Dr. Mekhail acknowledged that the study was very small and the results were preliminary. However, he said these encouraging results suggest that spinal cord stimulation may offer “significant therapeutic potential” for difficult to treat patients with severe, long-standing visceral pelvic pain.

—Betsy Bates

OvaCheck Unaffected, Developer Says

The serum proteomics study design debate won’t affect the progress of OvaCheck, a proteomics test being developed to screen women at high risk for ovarian cancer, said Peter Levine, head of the Maryland firm developing the test.

“This is a purely academic debate,” said Mr. Levine, chief executive officer of Correlogic Systems Inc. “It has no bearing whatsoever on the state of the development of the technology today or on any of the other work researchers have been pursuing in this field.”

OvaCheck uses a sophisticated mathematical algorithm and mass spectroscopy to identify a specific pattern of serum proteins associated with even very early-stage ovarian cancers. The method was based on a 2002 National Cancer Institute (NCI) study, but it uses a different mass spectrometer and different spectral signals to identify cancer samples. Correlogic Systems is conducting validity testing on hundreds of samples but has not released any data on those tests.

The study design debate adds nothing to the development of proteomics technology because it focuses on outdated research, Mr. Levine said. “These studies are 2 and 3 years old,” he said. “Since then, scores of additional papers have been published on this technique and variant.

In fact, reanalyzing older studies may put forth the mistaken impression that serum proteomics has no future as a screening or diagnostic tool.

“Serum proteomics is in its infancy in the way we look at this biological data,” he said. “It was just a proof-of-concept study. No one ever claimed it was a test for ovarian cancer.”

Many additional, more recent studies continue to expand on this original idea, including the research Correlogic Systems is performing, Mr. Levine said. “We are refining our own technology as we go through the testing process, and that kind of research and development—tweaking the equipment and the process—goes on forever, as it should. Continuing to debate these early papers is like doing a thesis on the Wright brothers’ first flight, when you already have a 747 that flies.”

OvaCheck, however, is still struggling through administrative processes at the Food and Drug Administration. Correlogic Systems hoped to license OvaCheck as a lab-developed test regulated under the Clinical Laboratory Improvement Amendments (CLIA). But the FDA determined last year that the software powering OvaCheck is a “dual” device, subject to external factors, such as changes in software, that Dr. Mekhail said would not be subject to external factors.

The problem, Dr. Baggerly asserts, is that serum proteomics has no future as a screening or diagnostic tool.

“The [NCI study] ushered in a revolution in the way we look at this biological data,” he said. “But it was just a proof-of-concept study. No one ever claimed it was a test for ovarian cancer.”

Many additional, more recent studies continue to expand on this original idea, including the research Correlogic Systems is performing, Mr. Levine said. “We are refining our own technology as we go through the testing process, and that kind of research and development—tweaking the equipment and the process—goes on forever, as it should. Continuing to debate these early papers is like doing a thesis on the Wright brothers’ first flight, when you already have a 747 that flies.”

OvaCheck, however, is still struggling through administrative processes at the Food and Drug Administration. Correlogic Systems hoped to license OvaCheck as a lab-developed test regulated under the Clinical Laboratory Improvement Amendments (CLIA). But the FDA determined last year that the software powering OvaCheck is a “dual” device, subject to external factors, such as changes in software, that Dr. Mekhail said would not be subject to external factors.

The problem, Dr. Baggerly asserts, is that serum proteomics has no future as a screening or diagnostic tool.

“The [NCI study] ushered in a revolution in the way we look at this biological data,” he said. “But it was just a proof-of-concept study. No one ever claimed it was a test for ovarian cancer.”

Many additional, more recent studies continue to expand on this original idea, including the research Correlogic Systems is performing, Mr. Levine said. “We are refining our own technology as we go through the testing process, and that kind of research and development—tweaking the equipment and the process—goes on forever, as it should. Continuing to debate these early papers is like doing a thesis on the Wright brothers’ first flight, when you already have a 747 that flies.”

OvaCheck, however, is still struggling through administrative processes at the Food and Drug Administration. Correlogic Systems hoped to license OvaCheck as a lab-developed test regulated under the Clinical Laboratory Improvement Amendments (CLIA). But the FDA determined last year that the software powering OvaCheck is a “dual” device, subject to external factors, such as changes in software, that Dr. Mekhail said would not be subject to external factors.

The problem, Dr. Baggerly asserts, is that serum proteomics has no future as a screening or diagnostic tool.

“The [NCI study] ushered in a revolution in the way we look at this biological data,” he said. “But it was just a proof-of-concept study. No one ever claimed it was a test for ovarian cancer.”

Many additional, more recent studies continue to expand on this original idea, including the research Correlogic Systems is performing, Mr. Levine said. “We are refining our own technology as we go through the testing process, and that kind of research and development—tweaking the equipment and the process—goes on forever, as it should. Continuing to debate these early papers is like doing a thesis on the Wright brothers’ first flight, when you already have a 747 that flies.”

OvaCheck, however, is still struggling through administrative processes at the Food and Drug Administration. Correlogic Systems hoped to license OvaCheck as a lab-developed test regulated under the Clinical Laboratory Improvement Amendments (CLIA). But the FDA determined last year that the software powering OvaCheck is a “dual” device, subject to external factors, such as changes in software, that Dr. Mekhail said would not be subject to external factors.