Diabetes in Men: Peer Support Boosts Control

BY DIANA MAHONEY

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MINNEAPOLIS — A peer-support intervention was associated with better diabetes control, compared with conventional nurse-led case management, in a 6-month Veterans Affairs study of men with poor glycemic control.

In the randomized prospective study, hemoglobin A_{1c} (HbA_{1c}) levels, insulin starts, and self-reported social support significantly improved in the 125 men with diabetes and HbA_{1c} levels higher than 7.5% who were enrolled in a peer-support intervention. The outcome measures did not improve in 119 matched patients who were randomized to usual care and conventional nurse-led case management, Dr. Michele Heisler reported.

Additionally, peer support was far less time intensive from a staff and resource perspective than other tested programs that have shown similar or less-significant improvements, Dr. Heisler said.

Blood pressure changes during the study were not significantly different for the two groups. Levels of diabetes distress and diabetes social support were assessed based on patient interviews, and new insulin starts were documented from patients' medical records.

For the study, all participants attended an initial session led by a Veterans Affairs (VA) nurse case manager, during which their baseline HbA_{1c} and blood pressure measures were reviewed and their questions were addressed, explained Dr. Heisler of the University of Michigan in Ann Arbor. After the initial meeting, patients assigned to the intervention arm participated in a group session designed to facilitate communication skills and help them set short-term goals for behavioral changes. Those assigned to usual care received nurse-led case management.

The demographics and baseline patient characteristics were similar in both groups. "The mean age of the predominantly white [82%] male veterans participating in the study was 62 years, and the majority [63%] had an annual income less than $30,000," Dr. Heisler said. At baseline, the mean HbA_{1c} levels for the intervention and control groups, respectively, were 8.03% and 7.93%.

VITALS

Major Finding: At 6 months, the mean hemoglobin A_{1c} of patients in the intervention group decreased from 8.02% to 7.73%, while the mean hemoglobin A_{1c} of the controls increased from 7.93% to 8.22%.

Data Source: Randomized, controlled trial comparing a peer-support intervention with conventional nurse-led case management in 244 men who had poor glycemic control and were treated in a Veterans Affairs program.

Disclosures: Dr. Heisler had no financial conflicts to disclose.

Age-matched patients were paired within the same cohort to serve as peer partners, Dr. Heisler said. "Patients were encouraged to call their peer partners at least weekly to provide mutual support and encouragement," she noted. "We developed a computer platform that enabled them to use their own phones to make calls without exchanging personal phone numbers, and it let us monitor and record the initiation, frequency, and duration of the calls. If patients hadn't made contact with each other within a week, they received reminders."

Intervention participants also were offered three optional 1.5-hour group sessions at months 1, 3, and 6. "Although these were nurse-led programs, they were completely patient driven and served as a forum for sharing concerns, questions, and strategies and for discussing progress on their action plans," Dr. Heisler said. In the control arm of the study, patients attended an educational session on nurse-led case management and were offered the services of a nurse case manager.

"At 6 months, the mean A_{1c} of the intervention patients decreased from 8.02% to 7.73%, while the mean A_{1c} of the control arm participants increased from 7.93% to 8.22%," Dr. Heisler reported. "We were especially concerned about patients at high risk, so we did a stratified analysis, looking specifically at the change in A_{1c} at 6 months for those patients with a baseline A_{1c} higher than 9.0% and the differences remained significant." Specifically, in the latter analysis, the mean HbA_{1c} decrease for intervention arm participants with a baseline HbA_{1c} higher than 9.0% was 0.88%, compared with a decrease of 0.07% in the control group, she said.

Regarding secondary outcomes, "we did see a 3.4% reduction in blood pressure results for the intervention group, but the differences compared with the control group were not statistically significant," Dr. Heisler said. "Also, there were eight new insulin starts in the intervention group and only one in the control group, and the diabetes social support outcomes were significantly higher for the intervention group as well."

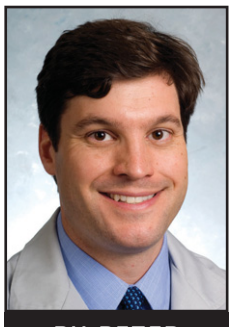
An evaluation of intervention participation showed that more than 90% of the peer partners made computer-facilitated weekly calls. Also, 40% of the intervention patients attended all three of the optional group sessions, while 25% attended two sessions and 12% went to one session, she said.

"This model is far less time and resource intensive than other tested programs that have led to similar improvements in A_{1c}," Dr. Heisler said. ■

GENETICS IN YOUR PRACTICE

Gene Patent Ruling May Have Far-Reaching Impact

The question of whether a gene can be patented has significant ramifications for clinicians, researchers, the biotechnology industry, and, of course, patients. On March 29, 2010, Judge Robert W. Sweet of the United States District Court for the Southern District of New York weighed in on this question in his summary judgment, which invalidated 7 of 23 patents covering BRACAnalysis, a test developed by Myriad Genetics to identify mutations in the BRCA1 and BRCA2 cancer susceptibility genes.



BY PETER HULICK, M.D.

In May 2009, the Public Patent Foundation and the American Civil Liberties Union, along with additional plaintiffs, filed suit against Myriad Genetics, the U.S. Patent and Trademark Office, and the University of Utah. The suit challenged the BRCA patent claims held, stating that they "stifle research that could lead to cures and limit women's options regarding medical care." Key organizations such as the American Medical Association and the American College of Medical Genetics supported this challenge.

One of the argument's key principles is that DNA is a product of nature, and products of nature are not patentable. In order to be patentable, a product of nature must undergo a change that makes it "markedly different" from its natural state. Myriad contends that isolated BRCA gene sequences obtained through purification meet this criteria because the DNA is separated from other gene sequences, proteins, and cellular components, thus making it sufficiently distinct from the naturally occurring state.

Judge Sweet ruled that isolated DNA does not meet the criteria, saying that "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an 'isolated' form alters neither this fundamental quality as it exists in the body nor the information it encodes." In other words, the significance of a DNA sequence is in the information encoded by the sequence, which does not change with purification.

The summary judgment also struck down the methods claims for patenting the analytical process of comparing an isolated BRCA DNA sequence with a reference sequence. The ruling states that because "comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter."

The ramifications of this summary judgment will be far-reaching. Approximately 20% of the human gene sequence is patented. Technology transfer offices at universities are certainly following such legal proceedings closely. Myriad has stated that it will "appeal the decision to the Court of Appeals for the Federal Circuit and will continue to vigorously defend this litigation."

Whether the patents will be stayed or suspended during the appeal process is not yet known. This decision also does not prevent another federal judge from ruling in the opposite manner, as it would at the Federal Circuit level. A decision at the Federal Circuit level would bind all federal courts, and likely this decision—regardless of the opinion rendered—would be appealed to the Supreme Court.

It is doubtful that in the interim there will be blatant disregard for the patent claims held by Myriad, based on this one decision. However, the door has been opened for researchers, clinical laboratories, and industry competitors to challenge the patent rights on the BRCA1 and 2 genes, as well as those on other genes currently protected.

Supporters of the litigation argue that if the decision is upheld, the change will lead to faster innovation and more research, while driving down costs associated with testing (currently more than $3,000 for the BRACAnalysis comprehensive test).

The potential to commercialize and advance clinical genetic tests based on next-generation sequencing also will be influenced by the final decision rendered in this suit. Genetic testing is beginning to move away from single-gene testing to incorporating whole panels of genes related to a particular disease or condition. If the courts broadly render genes to be unpatentable, potential legal hurdles in bringing personal genome sequencing to the clinical domain will be removed. On the other hand, losing the ability to patent genes may result in a loss of research funding for the biotech industry and universities conducting genetic research, and reduce the incentive to bring a test to market that ultimately benefits the patient.

Regardless of the outcome of the appeal, the debate will certainly continue. ■

DR. HULICK *is a medical geneticist at NorthShore University HealthSystem, Evanston, Ill., and a clinical assistant professor of medicine at the University of Chicago, Pritzker School of Medicine.*