

15th Annual Mayo Clinic Nicotine Dependence Conference 2008

Conference Report by Frank G. Mathers M.D.

The 15th Annual Mayo Clinic Nicotine Dependence Conference was held from April 28th to 30th 2008. The conference primarily focused on updated methods of treating tobacco dependence. Several presentations were given, including information about reduce-to-quit methods; harm reduction; suicide and suicide-related behaviors in relationship to smoking; and relapse prevention for pregnant smokers. Additionally, complementary treatments and environmental tobacco smoke were also discussed. The conference provided a particular focus on mental illness and substance abuse, as many mental illness patients are also smokers.

The aim of this report is to reiterate that nicotine dependence is not a lifestyle choice, but a chronic medical condition. This medical condition can be treated effectively when primary care physicians intervene by providing a variety of treatment options to patients who are undertaking smoking cessation. Additionally, health professionals such as nurses should also be involved, as they can be highly effective when integrated into a physician-lead system of motivational patient interviewing and counseling.

Patient Assessment

Patient assessment is a standardized step in treating the smoker. Several areas must be assessed before an appropriate treatment can be determined. These areas include dependence level; tobacco type and amount used daily; stressors that lead to smoking in the person's life; the person's motivation to quit smoking; and whether the patient has previously attempted to quit. Additionally, there may be barriers, coping issues or support issues that come into play when an individual is attempting to quit. Systematic inquiries during patient assessment include whether the individual is depressed or regularly uses alcohol. Alcohol and smoking tend to be two conditions that go hand-in-hand, as smokers who drink tend to increase their amount of smoking and vice versa. Many individuals have found that they also have to give up alcohol in order to give up smoking due to this relationship. Other areas of assessment include substance abuse and psychiatric disorders.

Ascertaining psychiatric disorders is a very important aspect of patient assessment. As the conference's special focus targeted psychiatric patients, it was noted that approximately half of all smokers in the United

States suffer from an additional addiction, and that the vast majority of all psychiatric patients are smokers.

Treatment for Addiction

Michael V. Burke, Ed.D. provided a presentation regarding the Mayo Model of Treating Tobacco Dependence. The model uses several key treatment components, one of those being motivational interviewing.

Motivational interviewing at the Mayo Clinic includes three main components. The first is collaboration between patient and physician. This is an important aspect, as only the patient is an expert on himself or herself. The second is evocation. The physician assures the patient that he or she has what it takes to quit smoking; the physician helps build self-efficacy in the patient. The third component of motivational interviewing is autonomy, which stresses that the patient has the right to choose and the capacity to decide to quit smoking.

Additional key treatment components are used at the Mayo Clinic. First and foremost, it is vitally important to realize that nicotine is a highly addictive substance that changes brain chemistry. As a result, quitting smoking is extremely difficult, and many patients need additional assistance through various treatments that are available in addition to motivational interviewing.

First-line Pharmacotherapy options now include Varenicline:

- Nicotine Patch
- Nicotine Gum
- Nicotine Lozenge
- Nicotine Inhaler
- Nicotine Nasal Spray
- Bupropion
- Varenicline (Chantix)

In Germany, motivational interviewing is a common aspect of treatment, in addition to prescribing drugs such as Varenicline. However, in Germany we have seen a reluctance from physicians to prescribe the drug due to time constraints and lacking reimbursement. The gold standard for nicotine addiction treatment is a combination of highly effective drugs and motivational interviewing to encourage relearning.

Practically all conference participants agreed that the time requirements for cognitive-behavioral interventions, such as motivational interviewing, have had to be adapted to the individual health care setting. Some participants

offered anecdotal reports of minimal cognitive-behavioral interventions accompanied by a Varenicline prescription and three follow-up office visits over a three-month period. I found this particularly interesting for the German situation. In Germany, patients face rigid budget constraints imposed on physicians as a standard fee per patient and quarter. The US has seen a drop off of follow-up Varenicline prescriptions after the initial four-week starter pack. In Germany, the effect has been more dramatic due to marketing a two-week starter pack. The United States has counteracted by offering \$30 rebates on a complete three-month course of the drug. Legal constraints would prohibit this in Germany. It seems wise, however, to consider replacing the two-week starter pack with a four-week version. From a scientific standpoint, higher smoking cessation rates would result from an extended application of the drug.

It has been found, however, that not all patients are able or ready to quit, even when treatment is combined with this large menu of pharmacotherapy options. However the Mayo Clinic has found several keys that should be utilized in the treatment process to help improve success rate, including:

- Allowing patients to tell their story, as this is meaningful to them.
- Motivational interviewing is effective, as it encourages the patients to continue.
- Patients are often encouraged by the disease model and should be encouraged to realize that they are indeed afflicted with a chronic medical condition rather than simply a poor lifestyle choice.
- Patients have different perceptions of what the quitting process will be like and what their experience will be, making education an important aspect of treatment.
- The patient's personal relationships are important, and support options should be considered in the treatment plan.
- The patient's environment is an important aspect of success rate, and it should be conducive to quitting.

- The patient's environment should attract support, promote positive action, provide emotional access and offer assurance throughout the quitting process.

Varenicline Trial Information

J. Taylor Hays, M.D., Associate Director of the Nicotine Dependence Center at the Mayo Clinic, provided a presentation about Varenicline, including background about developing the drug and information regarding its efficacy. According to Dr. Hays, the drug was developed due to the fact that long-term abstinence from smoking has resulted in very low long-term results, as most smokers tend to relapse. However, when presented with a new treatment option, many chronically afflicted smokers are encouraged to try quitting smoking.

Dr. Hays reported that Varenicline trials found that the higher the dosage, the more effective the drug was. The self-titration study found that Varenicline elicited fewer side effects, particularly reduced nausea, as compared to other study results. Additionally, the prescribing information provides us with more details about the drug, one important aspect of this being no interaction with diabetes drugs or heart medication. No dose reduction is required for geriatrics or patients with liver disease. These two features are very important, as many patients who smoke also drink alcohol, even after suffering from serious health maladies as a result of drinking alcohol. This information is also important because many patients must quit smoking due to health conditions such as diabetes and heart conditions; Varenicline is a reliable and effective drug that can be utilized for smoking cessation while treating both conditions.

According to Dr. Hays' presentation, Varenicline is an effective method in treating nicotine dependence. The side effects of Varenicline are also generally mild and well-tolerated. This is important, as many patients experience anxiety about quitting, simply because they don't know what to expect when beginning a smoking cessation program and what sort of side effects they will experience. Varenicline was also reported to be effective as a first-line treatment for tobacco dependence as well.

Reduce-to-Quit Concept and Varenicline

Reduce-to-quit is a common method of smoking cessation. Smoking reduction to promote cessation is achieved by patients reducing the amount they smoke until they reduce to a level when they are able to set a quit date and abstain from that point forward. According to the presentation regarding this form of treatment, the prevalence of smoking in United States adults in 2006 was highest within the age group of 18-24, at 23.9%. The age group of 25-44 was only .4% behind this group, at 23.5%. The age group of 45-64 was only 1.7% behind the second group, at 21.8%. Interestingly, the age group of 65 and older was significantly lower than all three previous age groups, at 10.2%.

There are several reasons for the spontaneous drop in smoking prevalence in the oldest group. First, chronic pulmonary disease in smokers begins to decline after age 49. Additionally, smoking prevalence declines with age; along with this, the median CPD is declining and continues to decline with age after age 50. However, significant spontaneous reduce-to-quit is uncommon overall.

The presentation about reduce-to-quit treatment provided evidence that quitting increases when a patient utilizes a nicotine replacement therapy method. Additionally, reduce-to-quit in conjunction with nicotine replacement therapy may increase long-term abstinence. Offering the option to reduce smoking slowly rather than abruptly is

appealing to many patients and may also encourage more patients into treatment. When this treatment option is combined with nicotine replacement therapy, attempts to quit and abstain from smoking increase. If patients need assistance in maintaining abstinence, they may be able to benefit from a drug such as Varenicline. When treatment involves Varenicline, physical cravings are reduced, making it easier on the patient to maintain abstinence.

Harm Reduction

Dorothy K. Hatsukami, Ph.D., Forster Family Professor in Cancer Prevention at the University of Minnesota's Tobacco Use Research Center, provided a presentation titled "Harm Reduction: A Wolf in Sheep's Clothing." This presentation explored the many different efforts that tobacco companies use to market "reduced exposure" and "reduced risk" products to smokers.

These products are considered to be a new generation of tobacco-based products that promise smokers reductions in exposure and risk. These products are aimed at health-concerned smokers interested in smoking cessation as well as addicted smokers who have been unable to quit. These products vary from cigarettes that are marketed as containing fewer carcinogens without losing the taste, to cigarettes that are marketed as having 80% less secondhand smoke with no lingering odor. There are even cigarettes that claim to be nicotine-free.

The sale and marketing of these products is possible because they are completely unregulated in the marketplace. Tobacco manufacturers are able to introduce or modify any product that they choose. They can also make just about any claim in order to promote their products. However, these products do nothing but confuse consumers as well as public health policy, as everyone believes that these are a "safer" cigarette.

Simultaneously, misconceptions still abound about "Light" and "Ultra-Light" cigarettes in the marketplace. These cigarettes are also marketed in a manner that can be confusing to consumers and lead them to believe that these types of cigarettes are actually "healthier" for them. According to Dr. Hatsukami's presentation, smokers believe that Lights afford a 25% reduction in risk compared to Regulars; and more than half of smokers believe you need to smoke two Lights and three to four Ultra Lights to absorb as much tar as from smoking one Regular. Dr. Hatsukami also made a good point by stating that 32% of Light and 26% of Ultra Light users say they would likely quit smoking if they learned that one of their cigarettes was equal to one Regular cigarette.

Dr. Hatsukami's presentation stressed a need for regulating the production and marketing of these products, stating that all claims should be scientifically based and tested so as not to mislead consumers, and marketed in a manner that does not result in greater harm. These products play one role in the marketplace: to keep smokers smoking rather than assisting them in the cessation process. Through dependence on these products, consumers often sustain tobacco use when they may have otherwise quit simply because they believe that these products make

smoking "healthier" for them. Additionally, these products may also cause individuals who have successfully quit to begin again.

Assessing Mental Health and Substance Abuse Issues in Tobacco Dependence Treatment

As previously mentioned, the conference provided a special focus on dealing with psychiatric patients and smoking cessation. Douglas Zeidonis, M.D., MPH presented interesting information regarding this subject. Tobacco dependence is often diagnosed with psychiatric disorders. In fact, an estimated 44% of all cigarettes in the US are consumed by individuals with a psychiatric disorder. Additionally, these individuals spend an estimated \$256 billion on cigarettes annually. Another interesting fact is that 75% of patients in addiction and mental health treatment programs are smokers, and most of them die due to a smoking-instigated disease. Schizophrenics are one group of psychiatric patients that are particularly underserved in nicotine addiction therapy. Schizophrenics in a psychiatric center or hospital are often allowed to smoke as a reward for good behavior; this isn't helped by the significant numbers of medical staff at these centers who smoke. This fact contributes to a change-resistant culture of nicotine addiction in these centers. Schizophrenics also have a shortened life span: 27 years less than the average population. The primary cause is an extremely high rate of cardiovascular and pulmonary disease due to smoking. Currently, approximately half of all smokers in the US also have an additional addiction or psychiatric diagnosis, with a vast majority of psychiatric patients smoking. This leads to another area of discussion: suicide and suicide-related behaviors.

The Effect of Smoking on Suicide and Suicide Related Behaviors

The objectives of the presentation by Timothy W. Lineberrys, MD were to describe the prevalence of suicide and suicide-related behaviors and how they are associated with smoking. Substance abuse and depression are the two main areas associated with suicide. Depression is responsible for 40% of suicide cases, while alcohol is responsible for approximately 25% percent of suicide cases. Also, individuals who are depressed are more likely to develop chemical dependence on substances such as alcohol and nicotine. On the other hand, sustained heavy alcohol use often induces depressive symptoms; 80% of patients with alcohol dependence report lifetime depressive symptoms. As noted previously, individuals who use alcohol also tend to be smokers.

Lineberry's exploration of smoking and suicide rates finds that psychiatric patients smoke at much higher rates. They also have clear mortality issues associated with smoking, but this is difficult to explore, as not much original research has been completed regarding psychiatric patients in relationship to smoking. Another concern is that Varenicline may be associated with some suicides related to nicotine addiction. This was made apparent when Lineberry included the FDA alert on Chantix in his presentation.

The FDA alert states:

Serious neuropsychiatric symptoms have occurred in patients taking Chantix. These symptoms include changes in behavior, agitation, depressed mood, suicide ideation, and attempted and completed suicide. While some patients may have experienced these types of symptoms and events as a result of nicotine withdrawal, some patients taking Chantix who experienced serious neuropsychiatric symptoms and events had not yet discontinued smoking. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following the withdrawal of Chantix therapy.

This FDA warning can create some concern for individuals who are already diagnosed with a psychiatric disorder and embarking on a smoking cessation program. However, psychiatric patients can quit smoking, as current smokers tend to be at a higher risk for suicide attempts than those who are quitting. Additionally, heavy smoking appears to be strongly related to suicide and suicide attempts, and it marks worsening periods of illness. This presentation makes it apparent that physicians and nurses should be particularly educated about this matter to actively work with patients to prevent these types of behaviors. Those who are able to recognize and respond to a suicide risk not only assist patients with their psychiatric condition, but also help them through their smoking cessation therapy to reduce the risk of smoking-related suicide. This presentation also makes it apparent that smoking is very common in these individuals; it presents clear dangers, as psychiatric illness and suicide are related, just as smoking and psychiatric illness are related.

Alcohol and Tobacco Use

One presentation that highlighted the importance of smoking cessation and how it can affect an individual's health in various other manners was presented by Richard D. Hurt, M.D. Hurt's presentation discussed the prevalence of alcohol and tobacco use, and the health impacts caused by the two combined.

According to Hurt's presentation, regular smoking usually precedes the development of alcoholism. There is also an increase in the prevalence of smoking among individuals who are addicted to other substances, and an even greater increase in the prevalence of alcoholism among heavy smokers vs. non-smokers. It is estimated that 26% of all smokers are also alcoholics.

With smoking and alcoholism, there is a higher risk for premature mortality. Even in alcoholics, tobacco-related diseases are a leading cause of death. This makes it imperative that tobacco dependence is treated in this high-risk group of individuals.

However, this group of individuals can be difficult to treat, as many have to give up alcohol and tobacco simultaneously. This causes the individual to experience physical withdrawal symptoms for both alcohol and tobacco at once, doubling the intensity. Nevertheless, the nicotine patch has been found to be an effective method for alcoholic smokers to quit. Alcoholic smokers are more nicotine-dependent than non-alcoholics, as they smoke and drink simultaneously; also, they smoke more as they drink more.

Through nicotine replacement therapy, these individuals are able to achieve short-term tobacco abstinence with nicotine patch therapy. There are those individuals who require more intensive therapy, including dose matching, longer treatment, increased behavioral intervention, and increased relapse prevention. This is due to the fact that alcoholics often experience depression; this needs to be treated to prevent suicide and suicide-related behaviors, as discussed in Dr. Timothy W. Lineberry's presentation about smoking and suicide.

Varenicline may be a viable option for use in these patients, as similar findings note the relationship between Varenicline and the nicotine patch in increased efficacy. Research showed that the nicotine patch was slightly more effective in treating these individuals, just as Varenicline in higher doses was more effective, as discussed previously in the Varenicline trials by J. Taylor Hays, M.D. However, it may be important for physicians and nurses to carefully watch the recovering alcoholic and smoker for signs of psychiatric issues and depression.

When treated together, alcoholism and smoking cessation therapy may be more successful. This is because drinking and smoking are closely related behaviors. Additionally, each of these chemical addictions is often a cue for the other. If alcoholics have a drink, they instantly experience a craving for a cigarette. By treating these two issues together, the cues to drink and smoke are eliminated; also, both types of treatment instill a similar message as to why both addictions should be treated.

Additionally, according to Hurt's presentation, tobacco dependence interventions provided during alcohol addiction treatment increase the long-term alcohol and/or drug abstinence by 25%. Smokers in treatment for alcohol addiction also show a greater willingness to stop smoking. Hurt also offered several recommended proven therapies for alcoholics quitting smoking, including:

- Nicotine Replacement Therapy
- Bupropion
- Varenicline
- Behavior Therapy
- Social Support

Hurt also stated that it is important to monitor patients frequently for relapse and to help patients realize that if they postpone treatment, they may never successfully quit smoking or alcohol.

Conclusion

In conclusion, the Mayo Clinic Conference provided a broad spectrum and depth of information. Varenicline was often discussed in presentations as a recommended treatment option for those embarking on smoking cessation therapy. The conference also proved my point of view that smoking is not merely a lifestyle choice, but a chronic medical condition that must be treated. Patients must have access to a physician, and the physician should work with patients to develop a plan to help them successfully treat their chemical dependency.

The Mayo Clinic's smoking cessation programs provide patients with a variety of support and motivational materials; this includes a workbook that allows patients to write the reasons why they need to quit and create a personal plan for how to quit. Physicians also have a variety of tools that they can utilize when creating this plan with patients, including drugs such as Varenicline or other types of nicotine replacement therapy. It is apparent that by simply working as a team, physicians and their medical staff members can help educate one other, educate the patient, then work together to ensure success in their smoking cessation programs.