

Clinical Perspective on Erectile Dysfunction Therapies

An interview with John P. Mulhall, MD, Assistant Professor at the Stritch School of Medicine and Director of the Center for Male Sexual Health, Loyola University Medical Center, Chicago.

Dr. John P. Mulhall has written extensively on male sexual function and penile reconstructive surgery and has had national network media exposure on “60 Minutes” and “Dateline.” He maintains several reviewing responsibilities with the International Journal of Impotence Research, Urology, Human Reproduction and the Journal of Urology, and also serves as a Section Editor for the journal Techniques in Urology.

AJMC: *Among available therapies, what do you consider to be the most and least safe?*

Dr. Mulhall: The concept of safety is very difficult to put into a nutshell. Sildenafil and apomorphine have nuisance symptoms—headache, facial flushing, and nausea. Penile implant surgery has rare side effects, but when they occur they are devastating. It’s very important to consider what the patient thinks is safe. When properly prescribed, all the available therapies are safe.

AJMC: *When does a relatively “safe” therapy become unsafe?*

Dr. Mulhall: When the symptoms are organ, health, or life threatening.

Symptoms such as headache, nausea, facial flushing, gastrointestinal upset—they are a nuisance but are not life threatening. It is a theoretical question because during trials the FDA [Food and Drug Administration] gathers data that decides if it will approve a drug or not. The burden of proof is on safety, not efficacy. ED [erectile dysfunction] therapies need only demonstrate a significant improvement in ED, not that someone can have sex.

AJMC: *How do primary care physicians’ treatment decisions tend to vary from those of specialists?*

Dr. Mulhall: Primary care physicians generally prescribe oral therapy because they are most familiar with it as a result of education through the media and the pharmaceutical industry, and it’s the therapy that has the lowest incidence of significant side effects. For a primary care physician to deal with something like a headache or nausea related to the use of oral agents is vastly different from dealing with someone who has priapism resulting from an injection. Also, the primary care physician generally sees patients whose goal is to get back to having sexual relations. Forty percent of the patients I see are 40 years of age or younger. They are very complicated and have different goals. They want to know the cause of

their ED problem. This calls for more investigation than would be required of a patient who simply wants to achieve an erection. Those patients are going for the simplest and least invasive approach. A specialist's patient population often dictates the necessity to investigate further.

AJMC: *What “off-label” therapy combinations are popular, and what is the danger of this practice?*

Dr. Mulhall: Currently, there is no frequently used off-label combination therapy. However, sildenafil has been used in combination with urethral suppository and in combination with implants. However, it is imperative that before any combination therapy is used on a regular basis that we have safety data on the patients who are using combinations. When apomorphine becomes available, many will want to use it with sildenafil. Until data becomes available that it is a safe practice, then it should not be used in that fashion. But I do believe that combination therapy will be at the forefront of therapeutic strategies in the future.

AJMC: *Should counseling always accompany therapy?*

Dr. Mulhall: No. Ninety percent of men have physically-based impotence. Most do not have any significant psychological component. Every man has a secondary psychological component because he is anxious that he will not be able to achieve an erection after failing to do so previously. But that is treatable by giving a therapy that gives a consistent erection. Those with relationship problems benefit most from therapy.

AJMC: *Are physicians, who are generally inclined to assume a clinical perspective, frequently reluctant to refer their patients for counseling?*

Dr. Mulhall: Primary care physicians are very unlikely to send patients for counseling. Remember, the goal of the sexual dysfunction specialist is not just to prescribe therapy that will enable a man to achieve an erection but to allow him to assume satisfactory sexual relations. That may be related to his erectile function but also to his stress level, his partner, etc. If I think the return of sexually satisfactory relations depends on therapy, then I will refer patients to sex therapists. The issue is not a rigid erection but is the patient satisfied.

AJMC: *Do most physicians consider the role of the sexual partner in evaluating erectile dysfunction?*

Dr. Mulhall: No. In fact, only 30% of patients ever get asked about sexual function by their primary care physicians. An even a smaller percentage of patients actually bring the topic up. About two thirds of my patients come in with a partner.

AJMC: *You cite penile injection as “the gold standard,” but are there risks associated with this therapy?*

Dr. Mulhall: When you inject multiple drugs into the penis, it works in over 90% of men—but it requires a direct injection into the penis. There is a low incidence of bruising and a 0.5% incidence of priapism, which is a urologic emergency. The side effects are limited to the penis; they are unusual and uncommon but all patients need to be counseled about them.

AJMC: *In your view, what mistake is made most frequently by providers surrounding the diagnosis and treatment of ED?*

Dr. Mulhall: Poor follow up would be the top on the list. A classic scenario is that a man walks out of the office with a prescription for sildenafil, he's

poorly educated about what it does and how to use it. And there's no follow up. The physician doesn't inform the patient that there are other options. At the clinic we see all of our patients at least every year. And they are eager to come in and talk about these issues.

AJMC: *Do you believe patients who present to their primary care physicians with sexual function problems should routinely be referred to a specialist for treatment?*

Dr. Mulhall: No. Indications for referral to a specialist include patients with: complicated endocrine, psychological, or psychiatric problems; penile deformity; medical or legal issues resulting from workers compensation claims, such as when ED is the result of lifting problems, back pain, or a popped disc. Patients who want vascular or neurological testing or who are potentially curable—typically 40% or less with the absence of risk factors—would also be referred to a specialist. If you don't find out if they're curable, they can stay on oral agents for years and years, which is not cost effective and not the right therapy.

AJMC: *In what ways has the introduction of oral agents revolutionized providers' approach to ED?*

Dr. Mulhall: Oral agents have revolutionized not just providers' practices but how patients and providers perceive ED. Physicians saw about 5% to 10% of men with ED 5 years ago. Today, it is about 25%. That number has more than doubled not only because we now have a palatable treatment, but also because of

patient education about the topic. It's changed how we perceive talking about sex. That will be the single most important factor. And I think the introduction of apomorphine will cause the number to jump yet again, bringing about 35% of all men with ED into our offices.

AJMC: *What is the impact of ED oral agents on men with normal sexual functioning? Are they being used to enhance performance?*

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Dr. Mulhall: We do not know. There have been no large randomized placebo-controlled trials, and oral agents are not indicated for men with normal sexual functioning.

AJMC: *Many believe ED is a natural part of aging. How aggressively should ED be treated in men 60 years of age and older?*

Dr. Mulhall: I would say as aggressively as we treat arthritis and osteoporosis and anxiety. Treatment of all of these conditions improves quality of life. ED is a cause of depression and marital discord and is a dramatic cause of decline in quality of life.