



Dr. Mark Noar: An Endoluminal Approach for Treating GERD

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Dr. Mark D. Noar is a Gastroenterologist and Therapeutic Endoscopist who specializes in the advanced treatment of digestive diseases. He completed his training in Gastroenterology at Downstate Medical Center/Brooklyn VA, in Brooklyn, New York. His training in Therapeutic Endoscopy was under the direction of Dr. Nib Soehendra, at the University Hospital in Hamburg, Germany. Dr. Noar has numerous publications and presentations to his credit, as well as inventions in Medical Simulation, Endoscopic Biliary Instrumentation and Electrogastrography. Dr. Noar is especially known internationally for his research and work in the field of endoluminal treatment for GERD, and the motility abnormalities associated with GERD.

Reflux1: When did you know you wanted to be a doctor?

Dr. Noar: In the fifth grade. There was no particular event that occurred; however, I think one reason was because my grandmother was seriously ill at the time. When I was a kid I was always the one playing the medic as opposed to the soldier. It just felt right for me.

Reflux1: How did you choose the field of gastroenterology?

Dr. Noar: When I was in medical school I did a rotation in gastroenterology. What impressed me was that was the diseases, diagnosis and treatments were very logical and physiological. It just felt like the right thing for me.

Reflux1: Can you explain some of your inventions?

Dr. Noar: Well in my early career I developed a series of medical simulators designed to teach people to perform endoscopy and gain experience prior to getting into the actual situation with their patients. This was quite a lively field in late 80s and early 90s that has essentially fallen by the wayside. We had a number of simulators in advanced biliary and pancreatic techniques as well as plain upper endoscopy and colonoscopy. I was not the only one in the field. There were a couple of others. We even had a couple of scientific symposiums that were developed. For the most part the field is quite small as this point, and there is an ongoing use now. We've moved away from the computer model, which, of course, was resource intense – it required a plug! And a computer. I went from simulation to then developing a porcine or live pig models for instruction. Using this model we ran a number of international courses to advance biliary and pancreatic techniques. At this point in time, medical stimulation is now more of a curiosity than a tool.

Reflux1: What kinds of changes have you seen in the last five years for the treatment of reflux and GERD?

Dr. Noar: The last five years have been phenomenal for treating reflux. Up until five years ago we essentially had two options, other than lifestyle changes. There was a wonderful class of multiple medications called proton pump inhibitors and the surgical procedure called fundoplication for refractory reflux – although that had its own problems. The biggest change has been the development of endoluminal or outpatient endoscopic treatment.

Reflux1: Is the Stretta procedure endoluminal treatment?

Dr. Noar: Yes. Rather than using an incision with a laparoscope, endoluminal treatments are performed by putting an endoscope through the mouth. It's far less invasive. There's no anesthesia required. There's also no post-procedure limitation in terms of activity or returning to work.

Reflux1: How do you rate the various procedures for treating reflux?

Dr. Noar: I was the first to adopt these new practices outside of formal clinical trials, with particular reference to the Stretta procedure, so I've had an opportunity to evaluate every other technology that has come along since. With regard to other endoluminal procedures available, I made a conscious decision to turn away from the Enteryx procedure, which I did for two reasons. One is that I think the implantation of foreign bodies, unless we are talking about titanium implants, is fraught with a number of problems. The human body does not take well to foreign implants, and it will do whatever it can to remove them. We know this because we used to use cyanoacrylate, which is essentially crazy glue, to stop bleeding. The cyanoacrylate would form a mold of the blood vessel, and within several weeks, the body would react to and wall that material, after which it was spontaneously pushed off into the body and end up in the stool. Back before they had metal surgical clips, gallbladders were removed with standard sutures placed on the cystic duct. In some patients we would subsequently have to remove stones from the bile duct. At times a specific type of stone was found, called a suture stone because it has multiple arms. When this type of stone is pulled out, there would be a suture in the center of it, but the suture never existed inside the bile duct. Instead, the body had transported the suture into the bile duct, in an effort to remove it from the environment. Any foreign body implantation is really problematic since the body will react to it, and it will create an inflammatory response.

My greatest fear with Enteryx was that since this was a deeply placed implant below the submucosa there was going to be an inflammatory response that would cause erosion in nearby body organs – which is exactly what happened. While there may be a placement issue also involved, this was something the body reacted to irrespective to whether it was placed properly or not. For me it was always a concern.

Gatekeeper was pulled off the market for reasons that have yet to be made clear. There have been no extensive trials published so we don't have enough information in regard to side effects. To date everyone treated was within the study but the product was not officially approved.

Reflux1: What do you like about the Stretta technique?

Dr. Noar: One of the things I like about the Stretta procedure is that it's not a quick fix. It's not something that gives someone instantaneous relief from reflux. This is a procedure that is largely dependent on the reduction in nerves or nerve synapses in the sphincter muscle, and can take up to a full year before its final effect is seen. Typically we have patients who get better slowly over time but with sustained relief.

What attracted me as well is that there was a lot of basic science that came before the device was developed. There was a lot of research about reflux and the mechanisms of reflux. In order to have muscle contract you have to have nerves firing. For a sphincter, the normal resting state is contracted, so there is no nerve action required to contract the sphincter. In fact, it's the opposite. You need nerve action to relax the sphincter. Once that became clear that one of the problems occurring was too much relaxation taking place, the development of a device designed to destroy some of those nerves so the sphincter would stay closed in its natural state more often, made enormous physiological sense for me.

Reflux1: What's the learning curve for the Stretta procedure?

Dr. Noar: Probably about five cases. The reason is that we have developed good quality in vitro models that make it very easy to learn and perform the procedure. The only way you are permitted to perform a Stretta procedure, is if you are proctored by an experienced physician who has done the procedure. There is a great deal of control in the teaching. So it's a simple procedure to do and to the manufacturer's credit they require training before they will even sell you the device.

Reflux1: Are there any side effects from the Stretta procedure?

Dr. Noar: There are no sustained side effects. Immediately following the procedure some people might have some discomfort in the chest area that may last anywhere from 24 hours, perhaps up to two weeks is the longest I have seen. There is never any difficulty swallowing. Nausea and vomiting is not something we usually find. I would say just that chest discomfort is the most common thing that people report. There have been no long term side effects.

Reflux1: Do people need to get the procedure done again?

Dr. Noar: Not normally, but it is possible. We do have a subset of patients who actually began having symptoms again after 2-3 years. We have done second set of Strettas in a small selective group of these patients, and we find that as long as they responded to the first treatment, they respond quite well to the second Stretta. Another group of patients, who respond extremely well to the Stretta procedure, are in people who have had the surgical procedure of Nissen fundoplication and failed. These patients respond virtually 100 percent of the time.

Reflux1: Do you think we are seeing more reflux disease or have we just become better at diagnosing it?

Dr. Noar: I believe there is more and more reflux disease occurring.

Reflux1: Why is that?

Dr. Noar: I think it is due to a multitude of factors. Certainly one of them is dietary, which leads to issues of obesity, especially in the Western world where this disease is becoming rampant. Obesity clearly drives this disease, as does the overuse of stimulants such as caffeine-based products. But I think there is another equally important and frequently overlooked factor and that is stress. When we talk about the stressful lifestyle there is a significant increase in acid secretions. People are eating more; there's a tendency to swallow more when you are under stress, which promotes reflux. It's not unusual at all to see a patient with significant reflux, and by simply recommending stress reduction techniques – if they follow them – their reflux can improve significantly.

Reflux1: With all the Starbucks out there, do you think we are going to see younger and younger people with reflux?

Dr. Noar: We already do. Reflux among younger patients is already present. It is also important to realize that people who are older and have symptoms were refluxers when they were young. In my opinion, the only difference between someone in their 40s and 50s who has to take medication for their reflux is that when they were in their 20s they still had reflux but their bodies were young enough to repair the damage. I suspect we are seeing increased acid production through stress, overeating and obesity, which once again leads people to a continued prolonged disease state, which their body as a difficult time managing over a long period of time.

Reflux1: Are patients using the proton inhibitors eager to get off the medication?

Dr. Noar: There is data beginning in 1988 that shows extraordinary safety and efficacy for the proton pump inhibitors. So we are looking at a decade and a half of safety data for those medications. These drugs are very safe with regard to the patient. While there is a small group of patients who don't want to take medication, most of them are just as happy – if the medication is working – to take one pill a day. It doesn't bother them. As long as they have insurance to pay for the medication, and it doesn't cost them too much.

Reflux1: Do you see the Stretta technique eventually replacing the medications?

Dr. Noar: I don't think so. If we look at the number of refluxers in the country taking daily proton inhibitors, I think we are looking at approximately 40 million cases. Out of those 40 million adult refluxers, you have perhaps five or six million who are refractory to their medication. So they are taking at least two of these proton pump inhibitors per day and still having significant reflux. Again that's in the U.S. alone. Those are large numbers. Even if every gastroenterologist could perform the Stretta procedure, it would still take years and years to treat everyone.

Reflux1: That's a lot of heartburn!

Dr. Noar: Well that's just in this country alone. In some parts of the world such as the Middle East, like in Iran or Turkey, 25 percent of the population has significant reflux. Another vitally important group is children. This is probably one of the most tragic groups, because there are really not a lot of options available for them. The results from the typical procedures, such as the Nissen fundoplication, are uniformly horrible. Based on recent figures I've seen, there are probably four to five million seriously ill refluxing children in the U.S. alone.

Reflux1: Are they too young to have the Stretta procedure because they are still growing?

Dr. Noar: From some initial studies we have performed, it appears that the wall thickness of the esophagus is pretty much the same in adults and children. So, we are beginning to look at different subsets of children who might benefit from the procedure. But I must emphasize that we are really in the infancy of looking at the pediatric population. There was one reported study of the treatment of eight or nine children that was done in the age range of 8-10 in which they have seen some improvement. We are getting ready to do more extensive studies.

Reflux1: So is having an endoscopic treatment a last resort for adult refluxers?

Dr. Noar: The way I view the endoscopic treatment is you have to make a good faith effort to change lifestyle, and then you have to demonstrate that you are a treatment failure, in terms of medication use. So for me, I reserve the endoluminal therapy for those people who are still having significant reflux symptoms despite taking at least two of the proton pump inhibitors class of medication, and showing a good faith effort with control of lifestyle.

Reflux1: How does that go over with patients when they come to see you and you tell them to lose weight and clean up your lifestyle? Aren't most people looking for a quick fix?

Dr. Noar: Everyone is looking for a quick fix. Most of the people are never going to achieve those lifestyle changes. However, those who succeed usually see significant improvement in their reflux symptoms.

Reflux1: Why is that?

Dr. Noar: In a word... Stress. It's too difficult to change. In the western world, we live in the horn-of-plenty, and it's very difficult for people to change what has become a habit over the years. Overeating is the result of trying to satisfy some of those stressors. We live a very fast-paced lifestyle, and you are expected to have high productivity. You are expected to do more and more. People are holding down multiple jobs. It's hard to stay awake without stimulants.

Reflux1: Have you had any patients who followed your advice and no longer needed the surgery?

Dr. Noar: Oh yes, and it's an interesting group of patients. With some patients who were actually scheduled for the procedure, I have about half a dozen who failed to show up the day of the procedure. We never heard from them. Then about a year or two later, I ran across them, and asked them what happened. They will tell you that instead, they changed their diet, controlled the stress, eliminated caffeine, chocolate, weren't drinking alcohol any longer, lost a bunch of weight, and they felt the best they ever had in their entire life and had no symptoms. So it does happen.

Reflux1: How knowledgeable are your patients when they come to you?

Dr. Noar: The vast majority of them will know a little bit, such as, "I understand there is a new procedure that doesn't require surgery to fix my reflux." But that is about the extent of it. We use a series of visual aids on videotape or CD, as well as printed material. Then we spend a lot of time explaining to them why we are doing this procedure, and provide them with the expectations of what happens after the Stretta procedure.

Reflux1: Do you think we expect more because of all the new technologies being introduced to the public via the media?

Dr. Noar: I think most people are skeptical when presented with the possibility of using this technique. The nice thing is that now when we are looking at the four year data, (we've done the two year and then three year prior to this), we are able to provide patients with numbers to help adjust their expectations. Since we don't know what the five year data is going to look like, I think that's why this procedure is not being offered to people with reflux who can control it with medication. When a patient is well controlled on medication, doctors are reluctant to offer the procedure. When the five-year data becomes available, we will have something more substantial and convincing to show.

Reflux1: What's so important about year five data?

Dr. Noar: Five years is kind of where physicians draw the line in the sand for durability of action. We are about to see enormous changes take place in this field of reflux and reflux correction, because at this point, we have the five-year data that shows these procedures are successful and cost effective. For the refluxing patient this is a great time, because they will have a number of alternatives they can turn to. Some people say that it's bad that Gatekeeper and Enteryx are gone. In fact it's actually a natural vetting of the developmental process. The safe and effective procedures will survive and rise to prominence. So this is fairly historic, considering what is about to happen in the field.

Reflux1: Do you have a favorite piece of technology that makes your job easier?

Dr. Noar: Just one? I would say if I had to point to one singular piece of technology that has made a huge difference is probably the computer. Only because we have much more rapid access to patient information, data analysis, and communication. That's something that has been a huge boon to us. Just the endoscope alone has been an enormous technological advance. To be able to look inside non-surgically, and see what's wrong without having to guess makes the endoscope a revolutionary and phenomenal tool.

Reflux1: What kinds of breakthroughs in the technology would you like to see in the future?

Dr. Noar: I would like to see a greater array of wireless devices that can be temporarily implanted inside of patients that would give us more information about what is happening inside the gastrointestinal tract. Now we take pictures, and we can measure pH. But there is a lot of what we don't know about the human gastrointestinal tract and how it is related to hormones and processes. To be able to map, locate and document, without having to be morbidly invasive would be a huge boon.

Reflux1: What do you consider your biggest challenge in treating reflux?

Dr. Noar: Nowadays it's the current insurance environment or reimbursement environment. There is a great deal we can do for people whether it be a medication or one of these endoluminal corrections techniques, but we still have such enormous reluctance and resistance on the part of the third party payers to pay for any of that. We have significant number of patients who can't find treatment or afford treatment because their insurance companies will throw up roadblocks.

Reflux1: Is that because they don't recognize reflux as a disease?

Dr. Noar: No I don't think it's that. There has been revolution in the last 10 years in the medical system in the country and spreading to others, where the insurance companies simply don't want to pay for anything. It's not just in the field of gastroenterology. The overriding environment is pay the least possible, if you have to pay anything at all.

Reflux1: Is your practice mostly referral?

Dr. Noar: Yes but there a number of patients who come to us because they have heard we do various things they're interested in. I literally have patients from around the globe who will call up and want to come in to have a Stretta procedure. There are probably more procedures done outside the U.S. overall. I think at this point it's well over 10,000 worldwide. Perhaps even close to 20,000.

Reflux1: How do you meet the challenge of staying up to date with all the new technology?

Dr. Noar: I think you just have to read, voraciously, everything that comes out from different places. I tend to focus on the literature around the world and literally everything that comes out from around the world and maintain an open viewpoint towards any new ideas. The other important thing is to spend a lot of time looking at the posters at major meetings. Usually the things that are selected for presentation have been digested for a number of years before they have reached a certain nexus where they are ready for prime time. Then they get accepted for presentation and publication. The new ideas, the new thoughts, which are not ready, are almost always in the poster sessions. And that's where you can pick up some phenomenal understanding of new processes coming along. It gives you an idea of what's going to work, what's not going to work, and what are some of the issues. It's much easier to pick technologies that will work.

Reflux1: How do you handle the demands of having a practice, doing research as well making inventions?

Dr. Noar: It is difficult to juggle so much. I am just a very high-energy person, who is excited by new ideas and processes. I admit that I do not sleep very much, and I just seem to turn the normal daily stress of life into productive energy. Most important is to surround yourself with a competent staff, always be open to new ideas, and never close your mind to anything. I am fortunate in that I don't seem to be affected by normal stressors as much as others. I can honestly say I don't have any reflux. I don't have any symptoms or illnesses. I don't take any medications. I guess I have different coping mechanisms. I thrive on it as opposed to being paralyzed by it.

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