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(866) 423-7849

Sedation and Endoscopy

SEDATION FOR ENDOSCOPY

You are listening to ReachMD, The Channel for Medical Professional. Welcome to GI Insight. We will recover the latest clinical issues, trends, and technologies in gastroenterological practice.

GI Insight is brought to you by AGA Institute and sponsored by Takeda Pharmaceuticals, North America. Your host for GI Insight is Professor of Medicine and Director of the Digestive Disease Center at the Medical University of South Carolina, Dr. Mark Delegge.

Our topic Sedation for Endoscopy, what is safe and effective. Joining us to discuss Sedation in Endoscopy is Dr. Larry Cohen. Dr. Cohen is an Associate Clinical Professor at the Mount Sinai School of Medicine in New York City.

DR. MARK DELEGGE:

Welcome Larry. Frankly, when I have my endoscopy I want to have some sedation. Currently, what is the most common sedation agents that are being used by gastroenterologist?

DR. LARRY COHEN:

Today, sedation really presents a blend of several different methods, as you know that the majority of gastroenterologists continue to give sedation themselves and they do it using a combination of an opioid, either Demerol or fentanyl along with benzodiazepine that is usually midazolam and that constitutes about two-thirds of all endoscopies to the best of our knowledge. The other third and that has to be probably approaching 40% at this point is sedation with propofol, and in most of the instances propofol is being given by an anesthesia specialist. So, across the country, about somewhere between 35 and 40% of all endoscopies in the US are done with propofol.

DR. MARK DELEGGE:

Now Larry, I have heard a lot about propofol, but can you give me kind of definition of that drug, and also I have heard about this conscious sedation or deep sedation or difference. Can you kind of set that apart for us?

DR. LARRY COHEN:

Sure. First of all, you know, historically when gastroenterologist and other non-anesthesiologist have given sedation, we practice to what we call conscious sedation what we now refer to as moderate or procedural sedation. Minor sedation just means that the patient retains a level of responsiveness, so that they can respond appropriately to either verbal or a light tactile stimulus, so that they are responsive, they can have a purposeful response to one of the stimuli. That is what we mean by purposeful by moderate sedation and binocularly describe it as responsive to shake and shout, okay. In contrast, deep sedation is where patient no longer response to those stimuli and it takes a painful stimulus to awaken them and for them to make a purposeful response. In general, we strive to keep our patients, we meaning non-anesthesiologist, gastroenterologist, we try to target moderate sedation. The reason for doing that is that patients are moderately sedated maintains a stable airway, they retain the ability to breathe spontaneously and their circulation is preserved. So, that we are not risking some cardiopulmonary event during moderate sedation. As you know, propofol is a very ultra short acting, ultra rapid acting, sedative hypnotic agent that has no real analgesic properties. It is a pure hypnotic agent, but has a very, very rapid onset of action. This onset of action is essentially the circulation time between arm and brain. So, the onset is somewhere between 15 and 45 seconds. So, from the time you give a bolus of drug to the time patient responds to about 15, 30 seconds. So, very, very fast, but also very short acting. Those both tend to provide benefits for short procedures like endoscopic exams.

DR. MARK DELEGGE:

Well, with that all Larry, why do you think gastroenterologist like propofol?

DR. LARRY COHEN:

I think the analogy is like the analogy when you compare driving a Chevy or a Ford to driving a sports car, you know they both get you from point A to point B, but for some reason, there is a certain level of attraction whether it is the speed, the excitement, the patients like the effects of propofol, they like both the way it puts them to sleep in a gradual way. When they are awaken, they get ahead as kind of so called clear headed recovery. They awaken very quickly and were able to often to sort of resume their normal activities within the couple of hours. So, again, I think that there are many gastroenterologists, who are perfectly, perfectly happy and satisfied using benzo and opioid combinations, but I think that for many of us having been had the opportunity to watch and perform exams with propofol, I think we see some of the benefits both to the patient as well as to the endoscopy unit in giving a short-acting agent. Patients like it because of their sleep, docs like using it because it helps make the sedation experience some more satisfactory one. It also may help to increase throughput through the endoscopy unit.

DR. MARK DELEGGE:

Now, Larry what are the issues in the endoscopy suite has always been difficulty when you are faced with the patient, who is on will say narcotics at home or benzodiazepines or frankly drinks a lot of alcohol. When you are using these types of agents like propofol, is there any advantage in this group?

DR. LARRY COHEN:

Well, yeah, there is. It is an interesting topic, you know we sort of label this group of patients more I guess, patients that are "difficult to sedate" and there are certain subgroups that we think about the alcoholics, people that are chronically using sedatives, sleep hypnotics, analgesics, pain killers, and so on, they are sort of historically been a group of patients that are very difficult to sedate with the drug like

propofol, though much of that melts always. It is almost unheard of today with propofol to have a patient that cannot be adequately sedated with propofol. In contrast, as you know, about somewhere between 5 and 15% of patients that come through a standard endoscopy unit, you know, fit into this category of the hard-to-sedate patient and when we say hard to sedate, we are not necessarily talking about patients that are at medical risk, not talking about high risk patients that are medically unstable, we are talking about people, who you give high doses of opioid and benzo. Say you give 100 mcg of fentanyl and you give 6 or 7 mg of midazolam, the patient is looking at you like nothing has happened. That is kind of patient that we are talking about and that almost never becomes a problem when you are using propofol.

DR. MARK DELEGGE:

If you are just tuning in, you are listening to GI Insight on ReachMD, The Channel for Medical Professionals. I am your host, Dr. Mark Delegge and joining me today to discuss sedation in endoscopy is Dr. Larry Cohen. Dr. Cohen is Associate Clinical Professor at the Mount Sinai School of Medicine in the big city of New York.

Larry, I have read the actual labeling of propofol and it talks about this drug being administered only by an anesthesiologist. From your perspective, is there data that says that the gastroenterologist could actually administer this drug in the endoscopy suite.

DR. LARRY COHEN:

There is a lot of data today, Mark that supports its use. I think, you know, if you look back historically at the use of propofol and you go back to its clinical development program, takes you back 25 years of the early 1980s and you look at clinical development program that led up to the FDA submission and approval. It was being developed by anesthesiologist for anesthesiologist, who was developed for induction and maintenance of anesthesia. There is a very important thing to keep in mind because what that means is that all of the preclinical studies that were done were done by anesthesiologist and they were done in the context of induction and maintenance of anesthesia. You know, the concept of MAC, monitored anesthesia care really did not come into play until 5 or 10 years later. So, the idea of doing short ambulatory procedures really was not an issue at that time. It was really never even imagined that it will be used for short procedures. It was really developed and so all the clinical data that was submitted to the FDA was based upon the anesthesiologist providing it inducing general anesthesia, and so the FDA simply ruled upon the data that was submitted and presented before them and since the studies were done with anesthesiologist for the induction of anesthesia, it made perfect sense that they would then come up with a label that indicated exactly what the clinical trials had undertaken.

DR. MARK DELEGGE:

With regards to the gastroenterologist specifically, is there data now published out there looking specifically at this question of the gastroenterologist delivering a drug without an anesthesiologist?

DR. LARRY COHEN:

Well, yeah, there are many studies in the literature. There had been studies published by somewhere, you know, investigators working in 18 to 20 different countries on virtually every continent in the world, which are investigators, you know ranging from academic University based investigators to community physicians working in their private clinics and offices. The experience is well over 500,000, which then brings up some of the safety data. A paper was presented and it has been completed and is being submitted almost as we speak paper that looked at the huge of worldwide experience with gastroenterologist directed propofol. This was a paper that was first authored by Dr. Rex and which he was able to cumulate more than 500,000 exposures to propofol that was administered by gastroenterologist and what he found in his huge experience and again this was a worldwide experience is that the administration of

propofol by gastroenterologist is as safe as the administration of propofol in the hands of anesthesiologist when used for MAC anesthesia and it is as safe if not safer than all the literature that has been published on the use of benzo, opioids for moderate sedation during endoscopic procedures. So that everything that is available and there is quite a bit of that out now, all of it indicates that gastroenterologist can use this drug effectively and at a safety profile in well over half a million patients. It is as good if not better than the safety profile for standard sedation agents by gastroenterologist or for that matter as good as the use of the same agent, propofol given by anesthesiologist for monitored anesthesia care.

DR. MARK DELEGGE:

Larry, this is an amazing topic. I would like to thank my guest from the Mount Sinai School of Medicine in New York, Dr. Larry Cohen for spending time with us today to discuss this very important and hot topic - Sedation in Endoscopy. Dr. Cohen, thank you very much for being our guest this week on GI Insight.

DR. LARRY COHEN:

You are welcome. Thank you.