

Response to the letter to the Editor

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Dear Sirs:

By means of this letter, I am responding to the letter sent by Dr. Martín Gómez in relation to our article "Determination of the frequency of hyperamylasemia and pancreatitis in patients undergoing endoscopic retrograde cholangiopancreatography" that was published by you in the previous issue of the journal.

I must admit how embarrassed I was when I read Dr. Gomez's reference to *Risk factors associated with pancreatitis and hyperamylasemia after endoscopic retrograde cholangiopancreatography (ERCP)* by M. Gómez, L. Delgado and V. Arbeláez in *Rev Col Gastroenterol.* 2012; 27: 7-20. (1) This excellent study was done by that important group that Dr. Gomez leads. When we did our bibliographic search, due to an inexcusable omission, the article in question did not appear. I think Dr. Gómez's reflection is important - he feels that his article should have been part of the references - because we have felt the same way many times when topics of stomach cancer and other pathologies that we have tried to manage and share have not appeared in such a prestigious journal and in publications of similar groups in national and international journals.

This is the perfect moment to apologize for our omission and to emphasize that Dr. Gómez's article is of the highest quality and is an undeniable Colombian production effort.

Articles sent to the journal for publication go through a strict process of evaluation by one or several peer reviewers who have frequently returned articles for lack of some classification. There is something similar in the text that we presented since we erroneously stated that there had been no publications in Colombia: in that sense the correction must be made. Apparently, the experts who evaluated the article, who are leaders in the field investigated, did not have the important article of Dr. Gómez and his group.

Another issue raised by Dr. Gómez that needs to be resolved is that the objective of the study was to determine the level of hyperamylasemia and pancreatitis in patients who had undergone ERCP rather than to explain how we avoid this complication. To clarify to Dr. Gómez as he requested, I would like to mention that we have strict processes that I will list.

- When the patient arrives in the wards, s/he receives an assessment from the anesthesiologist and the group.

- Hydration is verified and reinforced if needed with 1000 mL of intravenous fluids.
- Thereafter adequate hydration is provided during and after the procedure.

According to our protocol, all patients who undergo ERCP regardless of whether the procedure uses a pancreatic cannula or is pre-cut, are given a rectally administered non-steroidal anti-inflammatory drug (NSAID). If the guidewire goes into the pancreatic duct and is seen by fluoroscope, and assuming that its route is shown by the anomalous curve it makes, it is aspirated. If the fluid is supposedly pancreatic, the guide is removed. If the same thing happens again despite placement of tension on the papillotome, the guide is left in situ and a 5 French single-ended pancreas stent is used. At that time, cannulation is attempted over the stent. If this is unsuccessful, a precut fistula is created. This is our preferred method.

In most cases, we perform cannulation with a papillotome, but sometimes we try with a guidewire followed by a cannula or papillotome. When a papillotome is used, we advance without pushing or aggression, then we introduce the guide and make gentle movements looking for the axis to go to the bile duct. We never inject without knowing where we are, although many professors, including international ones (some of whom are included in the meta-analysis shown by Dr. Gómez) who have patients with pancreatitis greater than 9.7%, advance them and inject them. For me this point is vital because the canal of the pancreas is irritated if it is cannulated or if the pressure of the biliary pore increases. Both are variables that can cause pancreatitis. We do not allow our residents to override these rules, and we are strict about their compliance.

Regarding the very low rates of pancreatitis reported in our article, one of the points that Dr. Gómez questions, I want to confess that when we evaluated the results with our epidemiologist, Dr. Luz Elena Sepúlveda, whose analysis is rigorous, we were surprised by them. This forced us to review the database again and to reevaluate our results. As Dr. Gómez says, what is published by a group that is academic and is considered serious is what emerged in the research.

That work was the research required for the graduation of Dr. Fabián Rodrigo del Castillo as a gastroenterologist. Not all the research work delivered by our residents is sent for publication. In this case, the clear results, despite the small sample of patients (98 in a 3-month cohort), seemed like a reward for a job done with discipline, with the methodology used in our exams, with good judgment and within time limits, and which abided by our daily chant: "The papilla is your friend, we should not attack her, we should just touch her and pamper her." We know that the cohort is very small, it is a sample that was collected in only

three months. The results in no way reflect our superiority compared to others. On the contrary, they are an open door to perform a better job, and we will surely have more cases of pancreatitis over time. The result is real, but it could be a coincidence and plain good luck for our service, given the amount of time.

At this moment, we have Dr. Mario Jaramillo, a graduate of that large, well-respected school that is the National University, on our team. In addition, one of the residents on the surgery rotation, Dr. Jaime Giovanni Muñoz, maintains great admiration for Dr. Gómez's group. In academic reviews we have noted, in a judicious follow-up, that our rate of pancreatitis is very low, but that is the rate we have.

I do not believe that different populations have been handled in the research of Dr. Gómez and ours, and it seems to me to a certain extent a bit dangerous and risky to publicly suggest in a letter to the editor that the number of cases of post-ERCP pancreatitis should be greater for initial cannulations made by residents. I think that has its advantages and disadvantages because, although it is true that teaching must increase the operating time and secure equipment from damage, this should not affect complications. Even, surely without offense, the letter tacitly proposes a low exposure of residents or exclusive performance by teachers, and it is also mentioned, although it was probably a drafting defect, that the residents are possibly experts at cannulation.

In this case the Greek Hippocratic principle prevails among those of us who perform advanced therapeutic endoscopy: "primum nil nocere" or "primum non nocere": the first thing is do no harm.

I want to share a nice experience with you. Our center is private (Union of Surgeons S.A. S.). This center receives residents from the Gastroenterology program of the University of Caldas. Every day we have shifts dedicated to urgency and special procedures. Because we are a referral center for a small geographical area, we get patients from several nearby capital cities and towns which forces us to start the first shift from 5:30 a.m. to 8:00 a.m. every day and then to have another shift day in the afternoon. Our academic reviews are sometimes done at night, we make virtual reviews of other topics, and we have meetings to make important decisions.

From the moment residents enter the program, all residents start on the 5:30 a. m. shift. During the first six months they observe procedures, study what is published about them, and at the same time, the younger residents are exposed to elementary upper endoscopy. After this period, we allow them to begin performing supervised procedures with the duodenoscope with which they make a good number of entries. They achieve high quality entrances approximately two months before finishing their first year. Every day for the first six months, they observe entrances do dry runs in

the laboratory with damaged duodenoscopes. These gives them practice in the use of tweezers, instrument output, two wheels and a nail and the working channel. At 10 months of residence, first-year residents are allowed to place a basket or a papillotome under supervision near the end of a procedure and after the patient's problem has already been solved and when the patient's condition is not critical. These are cases in which the papillotomy presented no problem and which were done through the open orifice with a papillotome or dilatation balloon. Introduction of an attachment that does not aggravate or endanger the life of the patient is easy and low risk, and an anesthesiologist is always present.

Currently, our first year residents need one week to change levels. Since about 15 days ago, if after entering the papilla it appears that cannulation will be easy (although nothing is easy about it) we allow them to make an attempt to enter. Actually, at first there are few who can cannulate at the first attempt, but to our surprise, Dr. Giovanni Muñoz, managed to do it just a few days ago. He just started his second year on February 1, although he has one more year of daily exposure to ERCP.

When the resident starts the second year, always under supervision, this is the priority. At least in the morning session (which is common for all), they have one year to achieve ERCP. In the afternoons, there is always a second-year resident with us in the special room and sometimes two. In the same way, there is always a first-year resident and sometimes two, according to the schedules in other institutions.

We are governed by the fundamental principle that cannulation should be as non-traumatic as possible (like all schools). They can see that our daily phrases are: "The papilla must be pampered", "You cannot attack, look at the entry axis and where they are going", "Do not enter at any angle other than the axis", among others (the same presented by Robert H. Hawes and Jacques Devière in their recently published article in *Gastrointestinal Endoscopy: How I Cannulate the Bile Duct*. (2)

Regardless of a resident's need to learn, if after three attempts to enter have failed, the professor takes command. Most of the time, the professor returns the instrument to the student in training after cannulation so that the student can do the guided papillotomy, extraction of stones, placement of stents, and any other things which need to be done. Frequently, when there are difficulties, the teacher must take the instrument again and continue.

All of this experience is lived by residents for two years. Since they are residents of a surgical program, we are aware of the responsibilities of providing them with good technical background and enough exposure so that they can learn by steps and without as in a rotation of a few months (a situation that alters the opportunity and leaves you to rely on luck.)

Most programs in this country are like ours in that they allow their first year residents to observe for a few months, allow them to do duodenoscopy in the second year, and provide a ERCP rotation of between three and four months. In both tendencies, ours (permanently) and that of other schools (fixed rotations), the resident will always go out to make his own curve when he finishes. In our school we have a chat for graduates of gastroenterology in which cases are commented on daily. We participate in reviews of articles and evaluate complications. The experience has been rewarding, and we see that the preparation of the majority of residents is adequate. From the timely chat topic of pancreatitis we know that the percentage is also low in their practices in various cities.

To conclude, I know that metaanalyses of prospective studies are the best evidence, but there are many isolated studies like ours that are important and which have been published. I would like to mention only two. The first, published by Masci, Toti and Minoli in *Gastrointestinal Endoscopy* in 1997, showed the incidence of post-ERCP pancreatitis of 1.6% out of a total of 1,693 patients. (3) The second, from the same journal, was published by Peter Cotton in 2009. (4) It studied 14,497 patients who underwent ERCP and found a percentage of pancreatitis of 2.6% (a larger sample than that of the metaanalysis recently published by Kochar in 2015). (5) This is the one cited by Dr. Gómez in his letter. The authors of the two articles referenced are known researchers, academics, authors of important books in the area. Both are also directors of fellowship programs.

Sincerely,

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