

MARCO BRUNO: So a few years ago, with a team of I believe 13 hospitals in 11 countries, we did a multi-center trial to assess the efficacy of using fully covered metal stents in benign strictures, among which also patients with chronic pancreatitis.

GUIDO The study was a multi-center study, including 13 centers and in 11 countries. The centers were spread in Europe, South America, and Asia, and North America as well. So I think it's a good representation of the world. Australia, as well.

When we enrolled patients for the benign biliary stricture study, chronic pancreatitis was finally, the largest group of patients. That's why we focused on chronic pancreatitis. Also, because the best results are obtained in these kind of patients which are patients that still today, most of the time require surgical intervention.

MARCO BRUNO: It was a trial where we looked at of course, safety. A very important issue if you take these patients and if you use a new device. A very important stent remove ability, because the stent supposed to be in there in well time for about 9 to 12 months.

So removability was a very important issue. And of course, finally effectiveness. The percentage of patients in whom we managed to definitely resolve the stricture.

So the results after one year of stent indwell in patients with chronic pancreatitis was that we were able to resolve the stricture in 80% of cases. And that was either because the stent was in the common bile duct for 12 months, or the stent had migrated prematurely. But these two taken together, 80% of patients we achieved resolution of the stricture, which is very high if you compare that with historical results that we obtained with plastic stents where kind of the maximum success rate would be like 30% or 40%.

GUIDO Patients of this subgroup in the study of benign biliary stricture will follow that for years. Of course, even fully covered stents are not the panacea, are not the solution for every patient because they can migrate, because they can cause some problems and have to be removed earlier than planned. However, on an intention to treat basis, the results of three years are good for 60% of the patient. So 2/3 of the patient may be treated with this device and with this strategy.

If we go to the subgroup analysis, those patients that had the stent inside for a period enough long, let's say let's put it like that-- and those are the patients that have the best results. And we can expect a good result of more than 80% after three years of follow up.

MARCO BRUNO: So from that three year follow up of the fully covered metal WallFlex stent for a patient with chronic pancreatitis, we're very content, very happy with the results. Because when we started off with that first 80% of patients who were initially successful, there were only 17% of patients with stricture recurrence. So our intention to treat basis, if you recalculate that, we will successful eventually after three years of follow up is 66% of the patients, which is in these difficult to treat patients, difficult strictures, at least in my mind, a very successful result. It also means that in 2/3 of the patients, you avoid a surgical procedure, which is a big thing in these patients.

GUIDO Having a 80%-- more than 80%-- 83% of the patients free of clinical relapsing after three years, is an excellent
COSTAMAGNA: result. More than 80% is an excellent result because this is a chronic disease that has an evolution. And so it's not something that we can stop. Chronic pancreatitis goes ahead. So after three years, 80% of good results, I think is extremely good.

Of course, we have relapses that we can retreat. We can retreat with plastic or with another metal stents. Or we can decide in special cases that these are patients that have to be sent for surgery for a definitive treatment. However, going back to the results of this study, I really think that after three year, more than 80% of patients free of symptoms is an excellent result.