

Research Article

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Effectiveness of the use of Rectal Indometacin in the prevention of post - CPRE pancreatitis in the Naval Medical Center.

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Abstract

Keywords

Pancreatitis,
Indomethacin,
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Introduction: Currently, cholangiography endoscopic retrograde (ERCP) is one of the MOST Widely used diagnostic-therapeutic procedures in the management of biliary tract and pancreatic disorders. Pancreatitis after the procedure is The most frequent complication. Its prevalence ranges from 3.5% to 20% in high-risk patients. The use of non-steroidal anti-inflammatory suppositories (NSAIDs) has-been shown to be effective and safe, being a measure recommended by the latest prevention guidelines. **Objective:** To Evaluate the effectiveness of the application of rectal indomethacin in the prevention of post-ERCP pancreatitis. **Material and Methods:** 202 consecutive ERCP Patients Undergoing Were included. Two groups: Control group and indomethacin group. **Results:** he rate of post-ERCP pancreatitis had a reduction in the indomethacin group (5.9% vs 13%, p = 0.083). The relative risk (RR) was 0.45 (95% CI: 0.16-1.22), the relative risk reduction (RRR) 0.55 (95% CI: - from 0.22 to 0.84), the absolute risk reduction (ANR) 0.07 (95% CI: - from 0.02 to 0.14). **Conclusions:** Rectal indomethacin is a safe, effective and inexpensive measure to Prevent post-ERCP pancreatitis in Both high-risk and average-risk patients..

Introduction

Currently Endoscopic Retrograde cholangio pancreatography (ERCP) is one of the diagnostic / therapeutic procedures most commonly performed in the management of diseases of the biliary and pancreatic ducts. The post-procedure pancreatitis is the most common complication. It prevalence ranging between 3.5% and 20% in high-risk patients. (Andriulli A. et al. 2007) (Scott Tenner et al 2013).

Previously it considered the use of pancreatic stents as the primary measure to prevent post-ERCP pancreatitis. However, the placement of a pancreatic stent is not a simple procedure to perform and do not have the same availability in all hospitals. The need to prevent this disease entity leads to the implementation of various pharmacological agents, among which, nonsteroidal anti-inflammatory drugs (NSAIDs)

administered rectally are the most studied. In various clinical trials and meta-analyses are most effective demonstrated to reduce the prevalence and severity of post-ERCP pancreatitis.

The last clinical guide prophylaxis of post ERCP pancreatitis, published in 2014 by the European Society of Gastrointestinal Endoscopy, recommends the use of suppositories NSAIDs in every patient undergoing ERCP, regardless of the risk of pancreatitis post ERCP, with LOE 1 and a degree of recommendation A. Additionally, the guide is recommended to consider the use of pancreatic stents as complementary measure in patients with high risk of post ERCP pancreatitis (LOE 1, degree of recommendation). (Clotilde Fuentes-Orozco et al 2015) (Tenner S. et al 2013) (Mazaki T. et al 2014) Following various publications and recommendations of scientific societies, the use of these agents is being implemented as routine practice for most of the teams, initially for high-risk patients and nowadays also for those low risk, since there is evidence that these patients benefit from this strategy is safe and inexpensive. Having pancreatic stents causes higher cost to perform such procedures so it is not used as a ruin NSAIDs as agents for the prevention of pancreatitis post ERCP, until we decided to implement the use of rectal indomethacin in our study, because of the recommendations of the latest guidelines and positive evidence in this entity.

It is intended to demonstrate the effectiveness in applying rectal Indomethacin pre-ERCP benefiting patients who undergo the procedure, thus reducing to a minimum the incidence of this disease and the patient is treated on an outpatient basis as was expected from the beginning. Economically speaking, they would reduce costs in health care as a drug indomethacin is low cost and easy administration that does not require special monitoring or other attachments. So the results and impact that leads will be reflected in short time with a decrease in patients who are hospitalized for hyperamylasemia and post-ERCP pancreatitis.

In Mexico there is little literature on this pathology of considerable magnitude which represents significant economic demands and morbidity of special interest, besides that there is an adequate consensus which is prophylactic best treatment which is reflected in the multiple handlings pre-process. That is why this work in addition to demonstrating the effectiveness of prophylactic therapy with greater evidence used worldwide, also could represent a basis for the

unification of criteria at the Naval General Hospital of High Specialty (HOGENAES) in handling this type of patients.

Materials and Methods

This is an analytical and retrospective study of 202 patients who underwent ERCP between March 2016 and January 2018, prior to the deployment of rectal indomethacin and after its introduction in our clinical practice were included. The study was conducted in the area of Endoscopic Surgery CEMENAV.

Inclusion criteria:

Patients undergoing ERCP regardless of diagnosis or the risk of pancreatitis post ERCP.

Exclusion criteria:

- Under 18 years.
- Previous ERCP with sphincterotomy.
- ERCP for stent removal.
- Acute cholangitis and / or acute pancreatitis in progress.
- Hypersensitivity to NSAIDs.
- Renal failure (creatinine 1.4mg / dl).
- Active or recent (within 4 weeks) gastrointestinal bleeding.

ERCP was performed according to the technique descrita.²⁵ Patients received conscious sedation and placed in prone position. one duodenoscope Olympus TJ140 was used and cannulation of the bile duct was performed with the technique papillotome on guide. In all cases sphincterotomy was performed following the successful cannulation of the bile duct. In case of difficult cannulation, after repeated attempts and discretion by the endoscopist, a section of the roof papillary knife precut was performed to facilitate cannulation. The process continued with the objective of this (stone extraction, stent placement, etc.).

Data were collected in a database of Microsoft Excel. 100 patients studied in the period in which no indomethacin suppositories were used (December 2014 to January 2016) and studied in the period 102 in which the suppository (February 2016 to January 2017) was applied were analyzed. The suppository indomethacin 75 mg was placed within 30 minutes before or after the ERCP. the different characteristics of the patients (age, sex, comorbidities and other

factors that could influence the results) were analyzed. The post ERCP pancreatitis was defined as the presence of pancreatic type pain and elevated pancreatic enzymes three times above the normal value within 24 hours of the procedure, with the need for hospitalization beyond 24 hours. The result was analyzed retrospectively reviewed the medical history of the patients.

Statistic analysis

Data analysis was performed using SPSS v.20 software. For analysis of categorical variables chi-square test or Fisher was used, as appropriate, and for the continuous variables the Student t test. Significance was $p < 0.05$.

Results

The 202 patients studied were divided into two consecutive groups: 100 patients without indomethacin (control group) and 102 patients with indomethacin (indomethacin group).

With respect to demographic variables both groups were homogeneous in terms of sex, age, comorbidities and procedures performed programmatically. The exception was that there was a significantly greater number of hypertensive patients in the control group in the indomethacin group (60 versus 43 patients, $p = 0.017$) (Table 1).

Table 1. Demographic Variables

Variable	Indomethacin group	Control group	p
Age years, median (range)	63.2 (17-95)	65.8 (15-92)	0,34
Female n (%)	53 (51.9)	58 (58.0)	0,47
Hypertension n (%)	43 (42.2)	60 (60.0)	0,017
COPD n (%) 4	4 (3.9)	6 (6.0)	0,72
Diabetes n (%)	15 (14.7)	15 (15.0)	1.00
chronic renal failure n (%)	1 (1.0)	5 (5.0)	0.20
heart failure n (%)	2 (2.0)	9 (9.0)	0,058
Obesity n (%)	3 (2.9)	4 (4.0)	0,97
Smoking n (%)	35 (34.1)	44 (44.0)	0.20
Alcohol n (%)	8 (7.8)	13 (13.0)	0.33
Pancreatitis previous n (%)	11 (10.8)	15 (15.0)	0,49
Outpatient n (%)	17 (16.7)	14 (14.0)	0,74

Regarding diagnostics that motivated the procedure, the most common cause Choledocholithiasis was followed by tumors periampullary region. The distribution between groups was also homogeneous,

except that there are more cases of tumors of the proximal bile duct in the indomethacin group (7 vs. 0 patients, $p = 0.02$) (Table 2).

Table 2. Diagnostics according to aetiology

Diagnosis	indomethacin group	Control group	p
Choledocholithiasis n (%)	60 (58.8)	69 (69.0)	0.17
periampullary tumors n (%)	31 (30.4)	28 (28.0)	0,82
surgical injury biliary n (%)	4 (3.9)	2 (2.0)	0,69
n proximal tumors (%)	7 (6.9)	0 (0)	0.02
Pancreas divisum n (%)	0 (0)	1 (1.0)	0.99

No differences between groups in the risk factors of pancreatitis post ERCP were found except that the indomethacin group most frequently balloon dilatation

(16 vs. 3 patients, $p = 0.004$) was performed duration and was less procedure (26.0 ± 9.5 vs. 30.2 ± 7.3 minutes, $p = 0.0005$) (Table 3).

Table 3. Procedure performed

Process	indomethacin group	Control group	p
Stone extraction n (%)	54 (52.9)	61 (61.0)	0,31
Stent placement n (%)	36 (35.29)	24 (24.0)	0.10
ERCP failed n (%)	12 (11.76)	14 (14.0)	0,79
Ampulectomías n (%)	0 (0)	1 (1.0)	0.99
Validated risk factors			
Cannulation difficult n (%)	21 (20.6)	24 (24.0)	.67
Cannulation failed n (%)	12 (11.8)	14 (14.0)	0,79
Sphincterotomies n (%)	85 (83.3)	80 (80.0)	0,66
Pre-cut n (%)	19 (18.6)	17 (17.0)	0.90
Main pancreatic duct entrance n (%)	17 (16.7)	17 (17.0)	1.00
Contrast in the main pancreatic duct n (%)	1 (1.0)	4 (4.0)	0.35
Papillary dilation balloon n (%)	16 (15.7)	3 (3.0)	0,004
Duration (minutes), average (range)	26.0 (10-60)	30.2 (20-50)	0.0005

Associated morbidity procedure was represented primarily by episodes of acute pancreatitis, being slight in all patients, with 13 cases (13.0%) in the control group and 6 in the indomethacin group (5.9%) ($p = 0.083$). The relative risk (RR) was 0.45 (confidence interval 95% (95% CI): 0.16 to 1.22), the relative risk reduction (RRR) 0.55 (95% CI: - 0, 22 to 0.84), the absolute risk reduction (ANR) 0.07 (95% CI: - 0.02 to 0.14) and the number needed to treat (NNT) 14 (95% CI: 7- infinite).

Asymptomatic hyperamylasemia was observed in 25 cases (25.0%) in the control group and in 11 (10.8%) of indomethacin group ($p = 0.014$). The RR was 0.43 (95% CI 0.21 to 0.86), the RRR 0.57 (95% CI 0.14 to

0.79), the RRA 0.14 (95% CI 0, 03-.24) and NNT 7 (95% CI 4,2537,19) (Table 4).

3 cases of bleeding post ERCP were recorded: 2 in the control group (2%) and 1 in the indomethacin group (0.98%) ($p = 0.54$). These cases were diagnosed within 24 hours of the procedure by the presence of hair and drop in hematocrit with good response to medical treatment and the need for adrenaline injection endoscopically in a case. Furthermore, 5 cases of post ERCP cholangitis were recorded: 2 in the control group (2%) and three in the indomethacin group (2.94%) ($p = 0.66$). They all had good response to intravenous antibiotic treatment. No cases of perforation or mortality in this study (Table 4) were recorded.

Table 4. Morbidity and mortality

morbidity	Indomethacin group	Control group	p
Acute pancreatitis n (%)	6 (5.9)	13 (13.0)	0,083
Hyperamylasemia n (%)	11 (10.8)	25 (25.0)	0,014
Hemorrhage n (%)	1 (0.98)	2 (2)	0,54
Cholangitis n (%)	3 (2.94)	2 (2)	0,66
Drilling	0	0	0
Mortality	0	0	0

The results of a subanalysis dividing patients in high-risk, average risk is shown in Table 5. We consider high-risk patients to those presenting some of the risk

factors of pancreatitis post ERCP validated in previous studies. (Rustagi T. 2015)

Table 5. Subanalysis: high-risk patients and average risk.

	Indomethacin (n = 26)	Control group (N = 26)	NNT	p
	High risk (n = 52)			
Pancreatitis n (%)	5 (19.2)	8 (30.8)	9	0,52
Hyperamylasemia n (%)	3 (11.5)	10 (38.5)	4	0.05
	Indomethacin (n = 76)	Control group (N = 74)		
	average risk (n = 150)			
Pancreatitis n (%)	1 (1.31)	5 (6.6)	18	0.11
Hyperamylasemia n (%)	8 (10.5)	16 (21.6)	9	0.08

Risk factors were considered:

Major criteria (1 or more):

- Previous history of post ERCP pancreatitis.
- pancreatic sphincterotomy.
- Precorte (doing the same from the ostium and in the direction of the bile duct).
- cannulation difficult (more than 8 attempts at cannulation).
- Pneumatic Dilation without sphincterotomy.
- ampullectomy.

Minor criteria (2 or more):

- Female sex less than 50 years.
- recurrent pancreatitis (greater than 2 episodes).
- Entrance to the main pancreatic duct in more than 3 opportunities.
- Three or more injections of contrast to the pancreatic duct with at least one opacifique tail of the pancreas.
- excessive injection of contrast opacification of the pancreatic acini.
- brush biopsy pancreatic duct.

Discussion

The impact of post ERCP pancreatitis in morbidity and mortality and cost / availability of pancreatic stents, determine the effectiveness of drug prevention is important for our daily practice. In the literature already it has several clinical trials and meta-analyzes addressing this issue.

In 2003, Murray et al. They showed a statistically significant benefit to the use of diclofenac applied rectally in 220 patients prior to undergoing ERCP (6.4% prevalence of pancreatitis in the diclofenac

group vs. 15.5% in the placebo group [p = 0.049]). (Murray B. et al 2003)

In 2007 three studies also showed benefits. Khoshbaten et al. They showed a statistically significant benefit with rectal administration of diclofenac in 100 high-risk patients who underwent pancreatography (pancreatitis prevalence of 4% diclofenac vs. 26% on placebo [P <0.01]). (Khoshbaten M et al 2008)

Sotoudehmanesh et al. They found that the prophylactic administration of rectal indomethacin in low-risk patients have no benefits. Subgroup analysis of patients who contrast was injected into the pancreatic duct revealed a protective effect, but the sample was inadequate to draw concrete conclusions (pancreatitis prevalence of 2.3% vs. 18.6% indomethacin placebo [p = 0.014]). (Sotoudehmanesh R. et al 2007)

Nikhil R. Thiruvengadamet al. also demonstrated benefits in 150 patients, independent risk categories ERCP pancreatitis post (pancreatitis prevalence of 5.3% Indomethacin 16% vs. placebo [p = 0.034]). (Nikhil R. et al 2016)

Later, in 2012, Otsuka et al. reported significant results comparing rectal diclofenac vs. placebo (pancreatitis prevalence of 3.9% vs. 18.9% indomethacin placebo [p = 0.017]). (T. Otsuka et al 2012) In the same year, Elmunzer et al. published the most important clinical trial on the subject. These authors included a total of 602 patients and divided into two groups: 307 were rectal indomethacin post ERCP and 295 placebo. The prevalence of pancreatitis was 16.9% in the placebo group and 9.2% in the group with indomethacin (p = 0.03). However, in this work

we were also used prophylactically placing a pancreatic stent in over 80% of patients, which can skew the findings. (Elmunzer BJ et al 2012a)

In a clinical trial, conducted in 2015 by Andrade-Davila et al., 100 mg of rectal indomethacin were compared vs. placebo in 166 patients with high risk of post ERCP pancreatitis, with a significant difference in favor of the use of indomethacin (pancreatitis prevalence of 4.82% vs. 20.23% indomethacin placebo [$p = 0.01$, RRA 15 %, RRR 75%, NNT 6]). (Andrade-VF Davila et al 2015)

In 2008 by Elmunzer et al., Different meta-analysis on the role of NSAIDs in protecting post ERCP pancreatitis conclude that both indomethacin and diclofenac rectally, before or immediately after the procedure, reduce the prevalence of hyperamylasemia asymptomatic, pancreatitis and severity of episodes. (Elmunzer BJ et al 2008b) (Zheng MH et al 2008) (Dai HF et al 2009) (Ding X et al 2012) (Akbar A et al 2013) (Shi N et al 2015) (Sun HL et al 2014) (Takeo Yoshihara et al 2015) (Ahmad D. et al 2014) (I Puig et al 2014) (Li X et al 2014) (Kubiliun NM et al 2015) (F. Tse 2013) (Rustagi T. et al 2015)

A recently published included 4741 patients taken from 17 randomized controlled trials, a total of 466 pancreatitis post ERCP, confirming that NSAIDs rectally are an inexpensive and effective measure for preventing this complication ($p = 0.005$, RR 0, 55 [95% CI 0.40 to 0.77] and NNT 19). One of the main strengths of this study is the large number of patients, although the authors emphasize the heterogeneity of the different studies as a limitation. In addition, it was found that no significant difference between indomethacin and diclofenac , Between administration performed before or after ERCP ($p = 0.99$) or between high-risk patients and average risk ($p = 0.69$). (Luo H. et al 2016)

The results of the above studies led us to implement the use of indomethacin suppositories in our patients, we decided to compare results before and after treatment. We observed similar to literature results, as we were able to reduce by 7% absolute risk of pancreatitis post ERCP with good NNT of 14. While this profit attributable not reach statistical significance due to the small size of our population, difference is remarkable and we think that an alpha error of only 9% should be taken into account. Accompanying the results of the main objective, the prevalence of asymptomatic hyperamylasemia was significantly

lower, with an absolute risk reduction of 14% and excellent NNT 7. Despite the numerical dispersion involving the division into groups of a small sample, with the consequent loss of statistical power, the results of the subanalysis of patients with high and low risk allowed us to see that the decrease in cases of pancreatitis and hyperamylasemia is more pronounced with the administration of indomethacin, both in the percentage difference and in the NNT.

With regard to complications, they had a similar prevalence as reported in the literature, there were no differences between the two groups and all were mild.

Study limitations include retrospective design in which both groups of patients were not simultaneous and the small sample size, legible conditioned by the population. However, the homogeneity between the two groups of validating analysis allows comparison, avoiding potential confounding variables, and the differences are important to draw conclusions although statistical significance was not achieved the main objective.

Consistent with previous studies and meta-analysis, the application of rectal indomethacin in our environment is an effective, safe and inexpensive measure to prevent post-ERCP pancreatitis and asymptomatic hyperamylasemia in patients undergoing ERCP.

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