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Original Research Article

Randomized placebo controlled study of diclofenac as premedication for endoscopic retrograde cholangiopancreatography

Darshan V. Parekh*, Samir Rambhia, Mohan A. Joshi, Vineet Kumar, Vishwajeet Pawar, Monika J. Pohekar, Rohit Deshpande

Department of General Surgery, LTMMC and LTMGH, Sion, Mumbai, Maharashtra, India

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***Correspondence:**
Dr. Darshan V. Parekh,
E-mail: dparekh2108@gmail.com

ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is a complex procedure which is commonly performed at various centres. It causes considerable amount of pain and discomfort to patients, and various centres have their own protocols regarding its management. Authors aim to study the efficacy of intravenous diclofenac as a premedication to reduce the pain and discomfort during and after ERCP.
Methods: This was a randomized placebo-controlled trial evaluating 40 patients. The pain and degree of discomfort was investigated using a 4- point ordinal scale questionnaire.
Results: The use of intravenous diclofenac as premedication for ERCP significantly reduces pain and discomfort during and after the procedure.
Conclusions: Intravenous diclofenac should be used as a premedication for ERCP procedure as it significantly reduces the pain and discomfort during and after the procedure.

Keywords: Diclofenac, Endoscopic retrograde cholangiopancreatography, Premedication

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a common procedure used to diagnose and treat a variety of hepatobiliary and pancreatic conditions. ERCP has transitioned from a diagnostic test to a therapeutic intervention, with the complexity of cases becoming more challenging and the possibility of subsequent complications increasing.[1] It is being done at various centers, large and small, and many gastroenterologists and surgeons are taking specialized training to achieve competence and the necessary skills in this line of procedures.[2]

Although, ERCP is an invasive procedure and involves considerable amount of pain and discomfort to the patients, it is done as an outpatient procedure, or may require hospital admission.[3,4] Also, various centers/endoscopists have their own protocols of managing the pain and discomfort of the patient during and after the procedure.[5] It may be done under light sedation with other standard premedications or under complete general anaesthesia.[6] There have been various studies regarding this.

The sedation methods generally used involve narcotics, which if given in increased doses, may cause desaturation. There are other factors that may contribute to patient desaturation such as prone patient position and insufflation during the procedure. Hence, authors consider diclofenac as a safer supplement for this study.

At centre, authors use sedation with other standard premedications to conduct an ERCP. In this study, authors aim to study the efficacy of diclofenac (an NSAID commonly used as an effective analgesic in

various forms) as a premedication to reduce the pain and discomfort during and after an ERCP.

METHODS

This prospective randomized study was done on patients undergoing ERCP in LTMGH, Mumbai to evaluate the efficacy of diclofenac in reducing pain and discomfort during and after the procedure.

Study period was June 2018 to December 2018.

Inclusion criteria

All patients undergoing ERCP who give consent.

Exclusion criteria

Patients with deranged renal function tests, known case of asthma, known hypersensitivity to diclofenac and patients with any heart disease.

Informed patient consent was obtained. Detailed history of every patient was taken, and complete clinical physical examination was done. They underwent a central blood count, renal and liver function tests. A randomization list was used to allocate patients to ERCP with or without diclofenac as premedication. Allocated patients were given 75 mg diclofenac intravenously 30 minutes before the procedure. All patients received intravenous midazolam 5 mg, ondansetron 4 mg, hyoscine 20 mg, and pentazocine (diluted 1:3 in distilled water) 1 ml, as premedication just before procedure.

ERCP was be performed using a standard side viewing duodenoscope with a 4.2 mm channel (model ED- 530 XT; Fujinon). If the procedure was uncomfortable at any stage, patient was supplemented with IV midazolam 5 mg and/or IV pentazocine (diluted 1:3 in distilled water) 1 ml.

The patients were asked to score the worst pain experienced during ERCP, and their degree of discomfort immediately after, at 30 minutes and 60 minutes after the procedure using a 4-point ordinal scale (0= none, 1= mild, 2= moderate, 3= severe).

Proforma for record purpose was filled on the basis of data collected from the patients and quantitative data was expressed as mean±standard error. Fischer's exact test was used to analyze clinical variables between the two groups. A p value less than 0.05 was considered statistically significant.

RESULTS

A total of 40 patients were included in this study that were randomized equally in both groups. Both groups had an equal sex ratio and were homogenous in age (Table 1). The mean duration of procedure was similar in both groups (Table 1).

Table 1: Clinical data of patients of patients undergoing ERCP.

	Test (n=20)	Control (n=20)
Gender (male/female)	10 (20)/ 10 (20)	10 (20)/ 10 (20)
Mean age±standard error	51.2±2.18	53.2±1.42
Mean duration(mins)± standard error	47.25±2.87	44.8±3.69

The primary cause was choledocholithiasis with obstructive jaundice (17 patients). Other causes were advanced Ca pancreas (9 patients), post cholecystectomy CBD leak (7 patients), benign CBD stricture (5 patients).

1 patient of chronic pancreatitis with PD stones was in each group (Table 2). ERCP with stenting was performed in all patients.

Table 2: Diagnosis of patients undergoing ERCP.

Diagnosis	Test (n=20)	Control (n=20)
Choledocholithiasis with obstructive jaundice	7 (35)	10 (50)
Advanced Ca pancreas	5 (25)	4 (20)
Post cholecystectomy CBD leak	4 (20)	3 (15)
Benign CBD stricture	3 (15)	2 (10)
Chronic pancreatitis with PD stones	1 (5)	1 (5)

On comparison, IV diclofenac significantly reduces the pain during and after ERCP procedure as indicated by the p value being less than 0.05 (Table 3).

Table 3: Pain score with and without IV diclofenac assessed on a 4- point scale.

		Pain scale					P value
		0	**1**	**2**	**3**	**4**	
Worst pain	T	2	3	10	3	2	0.010
	C	6	2	1	4	7	
Immediately after	T	13	4	2	0	1	0.025
	C	5	9	3	3	0	
At 30 mins.	T	16	2	1	1	0	0.000
	C	3	3	8	6	0	
At 60 mins.	T	19	0	1	0	0	0.000
	C	7	8	4	1	0	

T: test, C: control.

DISCUSSION

The current study demonstrates that premedication with intravenous diclofenac prior to ERCP significantly

reduces the pain and discomfort during and after the procedure.

There are various studies for drugs used for sedation and analgesia for ERCP, although there is no defined protocol for the same. The present study is the first randomized report in literature about intravenous diclofenac used as an effective analgesic for the procedure.

In endoscopic procedures, premedication may have advantages such as reduction in drug demand for sedation, anxiolysis and induction and contribution to hemodynamic stability in conscious sedation procedures.[7] Outpatient procedures like ERCP, however, require that premedication drugs should be short acting, have sedative and analgesic contributions, not delay recovery and have minimal effect on cognitive function. As a consequence, benzodiazepines and analgesics are frequently used for this purpose.[8,9]

It is well known that diclofenac, a potent inhibitor of phospholipase A2 activity, administered immediately after the procedure, is effective at preventing pancreatitis.[10,11] It blocks the inflammatory cascade and that may be the reason for its efficacy in pain reduction.

ERCP is being increasingly performed at various centres in India, small and large. Since there are no protocols for anaesthesia, and due to limited resources of a lot of these centres, and a significant learning curve for the procedure, patients may end up getting notable pain and discomfort. Premedication with intravenous diclofenac is one way to reduce it significantly. It is easily available, cheap, well tolerated, and safe for the patient, making it a noteworthy premedication.

CONCLUSION

The results of this study indicate that intravenous diclofenac should be used as a premedication for ERCP procedure as it significantly reduces the pain and discomfort during and after the procedure. It should be used as a supplement to sedation and other analgesics. It is safely tolerated by patients, and is a cheap, and easily available drug for pain reduction.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of Department of General Surgery, LTMGH, Sion, Mumbai

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