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A COMPARISON OF INTRAVENOUS PARACETAMOL AND INTRAVENOUS DICLOFENAC SODIUM FOR POST-OPERATIVE PAIN RELIEF IN FUNCTIONAL ENDOSCOPIC SINUS SURGERY- A RANDOMIZED STUDY

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(ABSTRACT) AIM The study was to compare the efficacy of intravenous paracetamol for post-operative analgesia, opioid sparing effect and side effects with intravenous diclofenac in Functional endoscopic sinus surgery.

MATERIALS AND METHODS 50 Adults patients between 20 to 45 years were recruited. They received a standard anaesthetic technique including Fentanyl 2µg/kg. Patients were randomised to receive either intravenous paracetamol or intravenous diclofenac sodium. Visual Analogue Scale was assessed regularly at 0,10,20,30 mins,1hr,2hr,3hr,4hr,5hr,6hr during the postoperative period. Total dose of fentanyl and number of doses were also calculated. Incidence of post-operative complication (if any) were also studied.

RESULTS The protocol was successfully completed in 50 adults. There was no significant difference between intravenous paracetamol and intravenous diclofenac sodium initially during the first 10,20,30 mins and 1hr after the completion of surgery. Thereafter difference was statically significant with diclofenac group having higher VAS score at 2,3,4,5,6 hr.

CONCLUSION 1. Intravenous paracetamol 15mg/kg gives better post-operative pain relief, less incidence of side effects when compared to intravenous diclofenac sodium.

2. Total requirement of rescue analgesics was similar in both groups.

KEYWORDS :

INTRODUCTION

FESS is a minimally invasive surgery and is associated with a mild to moderate post operative pain. This is due to surgical trauma and nasal packing. Treatment is usually based on non -opioid analgesic with rescue analgesics.

IV paracetamol is one of the preferred drug due to an excellent safety profile. There are so many studies to show that iv paracetamol provides good analgesic in endoscopic sinus surgeries.

The purpose of the present study was to determine the post op analgesic effects of pre-emptive iv paracetamol and the amount of reduction in fentanyl consumption in FESS.

MATERIALS AND METHODS

After obtaining approval from ethical committee and informed written consent, 50 ASA physical status I and II patients aged 18-65 years, undergoing FESS were enrolled in the study. Patients with history of gastric bleeding, impaired liver function, impaired renal function, history of drug abuse, history of alcohol abuse, chronic pain patients receiving sedatives, analgesics and corticosteroids, history of prothrombotic tendencies, severe cardiovascular, hepatic or renal disease and mental illness were excluded from the study. Patients were trained about the usage of Visual Analogue Score for pain scores.

STUDY DESIGN

The study was a prospective, randomised, single blinded, case control study. 50 patients were selected and divided into 2 groups by randomization by lot method. Anaesthetic technique was standardized in all patients. In the OT iv fluids were started after cannulating with 18 G venflon. NIBP, ECG, and SpO2 were monitored. All patients were given Inj. Ranitidine iv to avoid GIT side effects with both drugs.

Patients were preoxygenated for 5 minutes. Inj. Fentanyl 2 mcg/kg, Inj. Glycopyrrolate 0.2mg, Inj. Xylocard 1.5mg/kg were given before induction. Induction was one with Inj. Thiopentone sodium 5mg/kg iv and Inj. Succinyl choline 1.5mg/kg iv. Patients were intubated with appropriate sized endotracheal tube and bilateral air entry was verified. For maintenance of anaesthesia, 1% isoflurane in N2O:O2 of (2:1) ratio was used. Inj. Atracurium 0.5mg/kg iv was used for muscle relaxation.

15 minutes before the end of procedure, Group P (n=25) received Inj. Paracetamol 1gm iv infusion over 15 minutes and group D (n=25) received Inj. Diclofenac 75mg iv infusion over 15 minutes. At the end of surgery, all patients received Inj. Neostigmine 0.04mg/kg and Inj. Glycopyrrolate 0.4 mg iv for reversal of neuromuscular blockade.

Patients were extubated after meeting standard extubation criteria. VAS scores were evaluated before shifting the patients to PACU. In the PACU, all vital signs were monitored and all patients received high flow oxygen via face mask. VAS scores were evaluated 10min, 20min, 30min after surgery and hourly up to 6 hrs post op. Later, VAS scores at 12 and 24 hrs were also evaluated. Rescue analgesic of Inj. Fentanyl 2mcg/kg was given if VAS scores were > 4. Total dose of rescue analgesics and side effects were documented.

OBSERVATION AND RESULTS

Fifty patients who fulfilled the inclusion criteria were enrolled in the study. The observations recorded from 25 patients each under paracetamol iv and diclofenac sodium iv administration were subjected in statistical analyses.

In order to ascertain the significance of demographic features, sample data were analysed using two sample students t-test, which exhibited no significant difference between Paracetamol and diclofenac sodium groups (Table-1). The duration of surgery was 58.60 ± 7.57 minutes in Paracetamol group and 62.40 ± 5.97 minutes in diclofenac group. The mean difference of 3.80 minutes was found statistically insignificant (p - 0.340NS)

Table 1: Demographic data and duration of surgery

Parameters	Paracetamol (n=25)	Diclofenac sodium (n= 25)	'P' Value
Male	13 (52%)	13 (52%)	1.000 NS
Female	12 (48%)	12 (48%)	1.000 NS
Age (yrs)	34.28+9.10	32.32+7.97	0.656 NS
Weight (kg)	56.68+10.45	56.84+7.14	0.261 NS
Duration of surgery (min)	58.60 + 7.57	62.40 + 5.97	0.340 NS

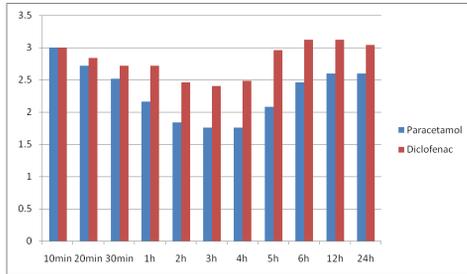
However, the t-tests conducted on VAS scores between two groups at different periods to ascertain the pattern and magnitude of difference had shown a notable picture (Table 2). The results indicated that there was no significant difference between paracetamol and diclofenac sodium groups initially during the first 10 min, 30 min & 1 hr after completion of surgery and thereafter the difference was statistically significant with diclofenac sodium group having higher VAS scores.

TABLE 2: VAS SCORES FOR POST OPERATIVE PAIN

Time (Duration after surgery)	Paracetamol group (n=25)	Diclofenac sodium group (n= 25)	'P' Value
T10 min	3.00 + 6.00	3.00 + 6.00	1.000NS
T20 min	2.72+0.46	2.84+ 0.37	0.316NS

T30 min	2.52+0.51	2.72 + 0.46	0.151NS
T1 h	2.16+0.47	2.36+ 0.49	0.148NS
T2h	1.84+0.69	2.46 + 0.50	0.002**
T3h	1.76+0.72	2.48 + 0.51	0.001**
T4h	2.76+0.72	2.96 + 0.54	0.001**
T5h	2.08+ 0.64	3.12+ 0.60	0.001**
T6h	2.46+ 1.12	3.12+ 0.33	0.007**
T12h	2.60+ 0.65	3.04 + 0.20	0.001**
T24h	2.60+ 0.50		0.001**

Graph 1: COMPARISON OF VAS SCORES BETWEEN THE TWO GROUPS



The t-test carried out to verify the significance of difference in fentanyl consumption among two groups also indicated no significant difference (Table 2)

Although the total fentanyl consumption was more in paracetamol group (260.00± 29.28mcg) than in Diclofenac sodium group (213.33±41.63mcg), the mean difference of 46.6mcg was found statistically insignificant. (p=0.440) NS. However, the number of fentanyl doses administered in diclofenac group was greater (2.33±0.58) than in paracetamol group (2.00±0.00)

GRAPH 2 : COMPARISON & TOTAL FENTANYL CONSUMPTION BETWEEN THE TWO GROUPS

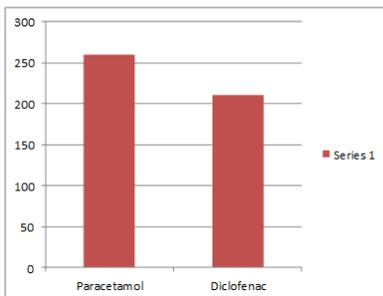


TABLE 3 : POST OPERATIVE ANALGESIC REQUIREMENT

	Paracetamol group	Diclofenac group	'P' Value
Total dose	260.00±29.28	213.33±41.63	0.440NS
Number of doses	2.00±0.00	2.33±0.58	0.053NS

The incidence of post-operative complication of nausea and vomiting in 8% of paracetamol treated group, while 12 %of diclofenac treated group exhibited the symptoms, the mean difference of 4% was found statistically insignificant. (p-0.637). The incidence of epigastric pain was noticed in 16 percent of diclofenac sodium group while none of the paracetamol treated group exhibited symptoms. The mean difference of 16% was found statistically significant. (P-0.037). Other postoperative complications such as pain on injection site, upper GIT bleed, sedation, hypotension, urinary retention, were not observed in both the groups.

Table 4: INCIDENCE OF SIDE EFFECTS

Complications	Paracetamol group (n=25)	Diclofenac group (n=25)	'P' Value
PONV	2 (8%)	3(12%)	0.637NS
Epigastric pain	0(0)	4(16%)	0.037*
Pain at injection site	0	0	
Upper GIT bleed	0	0	

DISCUSSION

The degree of pain reported after endoscopic sinus surgery was of moderate intensity , nonetheless , routine use of local anaesthetic infiltration or topical bupivacaine packing is not sufficient for the treatment of postoperative pain sparing effect .

Pain after nasal and sinus surgery is usually maximal in the first few postoperative hours. During this time, oral opioids are commonly prescribed but these drugs are frequently associated with adverse effects such as sedation, nausea, vomiting, urinary retention , pruritis and respiration depression (church,2006). NSAIDS are the most commonly used non- opioid analgesics for such purposes.

Sinatra Rs et al studied the efficacy and safety of single and repeated administration of 1gram intravenous paracetamol injection for pain management after major orthopaedic surgery.

They concluded that intravenous paracetamol 1g administered over a 24 h period in patients with moderate to severe pain after orthopaedic surgery provided rapid and effective analgesia and was well tolerated.

In our study there was no significant difference in the VAS score in between the paracetamol and diclofenac groups initially until one hour after the end of surgery and thereafter the differences were statistically significant, with diclofenac sodium group having higher VAS scores. The incidence of PONV was higher in diclofenac sodium group (12%), and was 8% in paracetamol group. None of the patients in paracetamol group exhibited signs or symptoms of epigastric pain while it was 16% in the diclofenac sodium group.

Murat el al, evaluated the relative analgesic efficacy of paracetamol with pro paracetamol during the 6 hr after inguinal hernia repair under GA with ilioinguinal block in children, They observed that, a single infusion dose of iv paracetamol 15mg per kg provides analgesia similar to single infusion of pro paracetamol 30mg per kg.

In our study paracetamol provides better postop pain relief when compared to iv diclofenac sodium.

Kemppainen Tatu et al , evaluated the incidence and severity of pain and efficacy and safety of paracetamol for pain management in patients undergoing FESS. 71 % in the placebo group needed rescue analgesics but 25% of patients in the acetaminophen group. There was no significant difference between groups in the incidence of adverse events. They concluded that acetaminophen provides adequate pain relief in most patients who have undergone FESS.

In our study paracetamol provides better pain relief when compared to diclofenac. There was no significant difference between groups in the incidence of adverse events, and the need for total analgesic dosage & consumption.

Alhashemi ja et al , compared the efficacy of intraoperative i.v paracetamol with i.m meperidine with regard to postoperative analgesia and readiness for discharge in paediatric patients undergoing day care dental restoration . They found that paracetamol group patients had slightly higher pain scores during early recovery compared with meperidine group patients. They concluded that the effect of iv paracetamol resulted in slightly higher pain scores but earlier readiness for recovery room discharge.

In our study iv paracetamol group patients had lower pain scores in comparison with iv diclofenac sodium and established its postop analgesic efficacy over iv diclofenac sodium.

Ahmed atef and ahmed Aly Fawaz et al, did a study to evaluate the analgesic efficacy and safety of intravenous paracetamol in patients undergoing tonsillectomy. Intravenous paracetamol significantly reduced pethidine consumption over the 24 hour period . There was no significant difference between groups in the incidence of adverse events. They concluded that intravenous paracetamol provided rapid and effective analgesia and was well tolerated.

In our study rescue analgesic dosage and consumption of fentanyl was the same in both the paracetamol and diclofenac groups. Paracetamol provide better postop pain relief in comparison with diclofenac.

J. Romsing et al, compared the analgesic efficacy of oral diclofenac and high dose paracetamol for analgesia in paediatric tonsillectomy

patients . The pain score was 5- 50 % in the diclofenac group , and 12-58% in the paracetamol group. None of the children in the diclofenac group experienced any episodes of nausea/vomiting compared to 9 children in the acetaminophen group . They concluded that diclofenac was no more effective than high dose acetaminophen (90mg vs 60 mg kg >24 h) for analgesia, but resulted in lower incidence of nausea and vomiting in patients following tonsillectomy.

Cattabriga I et al, did a study to analyse the effect of iv paracetamol as an adjunctive analgesic to a tramadol based background analgesia after cardiac surgery. At 12 , 18 , 24 h after the end of operation ,patients who received paracetamol had significantly less pain at rest (p-0.0041, 0.0039 , 0.0044, respectively); after this time the two groups did not differ. Paracetamol group required less cumulative morphine than placebo group (48 mg vs 97 mg), even if the difference did not reach statistical significance (p -0.274). They opined that in patients undergoing cardiac surgery , intravenous paracetamol in combination with tramadol is effective in pain control.

In our study, the total and number of fentanyl rescue analgesic doses required was similar in both the groups.

Md Jean Marty et al, conducted a study , to assess the tolerability and efficacy of a single dose of iv paracetamol 1g in comparison with a single dose of iv pro paracetamol 2g in patients with moderate to severe pain after minor gynaecologic surgery . They concluded that, in patients with moderate to severe pain after minor gynaecologic surgery, a single dose of iv paracetamol was associated with better tolerability, similar analgesic efficacy, and greater patient satisfaction .

In our study paracetamol was associated with better analgesic efficiency, greater patient satisfaction and low incidence of epigastric pain when compared with diclofenac.

Pertunen et al did a study to analyse the efficiency of continuous influence of diclofenac sodium in patients undergoing thoracic surgery . The results of their study showed that the consumption of morphine was reduced with 60%. Analgesia was also superior in the diclofenac group. They concluded that iv diclofenac sodium combined with opioids via PCA seems a valuable method of pain relief after thoracic surgery.

In our study, the postop rescue analgesic dose of fentanyl was similar in both paracetamol and diclofenac sodium groups.

Grace et al , did a study about the effectiveness of diclofenac sodium versus fentanyl for analgesia in laparoscopic sterilization. The results showed that neither diclofenac sodium nor fentanyl provide sufficient analgesia for laparoscopic sterilization when given as a sole analgesic.

In our study diclofenac sodium had higher vas score when compared to paracetamol showing the paracetamol provided better pain relief when compared to diclofenac sodium.

CONCLUSION:

1. Intravenous paracetamol 15mg/kg gives better post-operative pain relief , less incidence of side effects when compared to intravenous diclofenac sodium.
2. Total requirement of rescue analgesics was similar in both groups

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