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Research Article

A comparative study on analgesic effect of paracetamol and diclofenac in post operative care

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ABSTRACT

In post-operative care, a prospective comparative study was carried out for 6 months to assess the analgesic effect of paracetamol and diclofenac within 5 days of surgery. Patients were selected based on the inclusion and exclusion criteria. The pain assessment was done by using visual analogue scale (VAS). The adverse drug reaction was analyzed using Naranjo adverse drug reaction probability scale. Statistical analysis was performed using Graphpad InStat 3 software. '*p value*' less than 0.05 were considered to be statistically significant. 140 patients were enrolled in the study which was divided into Group P (Paracetamol) and Group D (Diclofenac). The mean age of female patients in group P were 35.7±.11.40 years and of male patients were 36.3±11.45 years, in group D the mean age were found to be as 38.2±13.85 years and 39.2 ± 14.2 years in female and male patients respectively. Gender distribution of patients showed that the majority of the patients (71%) were female. There was higher VAS score in Group P compared to Group D and difference was statistically significant (p <0.05). It was found that diclofenac was more effective in reducing post operative pain than paracetamol. From the different parameters compared and outlined in our study, IV paracetamol and IM diclofenac tends to offer adequate post-operative analgesia. Nonetheless from our study, it was established that IM diclofenac appears to be a superior post-operative analgesic compared to IV paracetamol. IM diclofenac is also safer in the post-operative period, which leads to reduced hospitalization and hence, cost effective.

Keywords: Diclofenac; Paracetamol; Post-operative period; Pain Management; Visual Analogue Scale; Naranjo adverse drug reaction probability scale.

INTRODUCTION

Surgery has become an essential part of the medical care system. Various studies shows that an estimated 234 million surgical cases takes place worldwide each year and the need for surgery is increasing each year with an estimated mortality of at least 0.4% and morbidity between 3% and 17% (Moonesinghe et al., 2011). Therefore post-operative management has become an essential aspect in current scenario and pain is a major challenge during and after surgery. Patient may suffer from both physiological and psychological pain. Hence, pain management is also as necessary as monitoring the pulse, blood pressure or temperature. Pain being a subjective phenomenon is perceived only by the sufferer. Hence, it has become the most important factors in determining when a patient can be safely discharged. Inadequately treated pain is a major cause of prolonged stays or unexpected hospital admissions after the surgery (Dawoodi et al., 2014). Surgeries are a burden to the body and pain can persist for weeks as the body works to heal. Unfortunately, most people cannot just put life on hold while their body heals. Activities like eating, working, moving and even breathing can cause pain, so they need to learn to control and manage the pain. That is easier said than done, as pain is unique, even if people go through the same surgical process, they may experience different pain afterwards as our brain and sensory nerves uniquely interpret signals. A mild pain experienced by one person may be excruciating to another (SSM, 2015). Pain involves four physiological processes: mainly transduction, transmission, modulation and perception. Pain begins when local tissue damage, a noxious stimulus occurs during the surgery, causing the release of inflammatory substances like prostaglandins, histamine, serotonin, bradykinin and substance P. This leads to the generation of electrical impulse at peripheral sensory nerve endings. These electrical impulses are conducted by nerve fibers like A-delta and C-fibers to the spinal cord. Further relate to higher brain centers can be modified with the spinal cord before an individual perceives a painful stimulus (Sodhi et al., 2004). Therefore effective pain management is an important element of post-surgical care. Many evidences suggest that surgery suppresses the immune system and that this suppression is in proportion to the invasiveness of

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the surgery. Therefore advantages of effective post-operative pain management include patient comfort and thereby satisfaction, earlier mobilization, fewer pulmonary and cardiac complications, a reduced risk of deep vein thrombosis, quicker recovery with less possibility of the development of neuropathic pain, and reduced cost of care (Kamtane et al., 2015). Surgeries are prevalent among both genders. But certain surgeries are exclusively to females like caesarean sections and other gynecological surgeries. Pain management in caesarean section is rather different from other surgeries as the person has to take care of her new-born also. Therefore a drug has to be chosen which cannot alter the person's conscious or put their obligations on hold. Moreover, drugs used for treatment or prevention of post-operative pain may affect the new-born through breastfeeding (Cancado et al., 2012). Analgesics can reduce this deleterious effect of the surgeries effectively. Local anesthetics are the best analgesics next to it are the high dose opioids, epidural opioids and clonidine (Kehlet, 1998). But as we consider efficacy and safety in post-operative care, major drugs satisfy this criterion includes paracetamol, diclofenac and newer agents like tramadol. Paracetamol 10 mg/ml Solution for infusion is indicated for the short-term treatment of moderate pain, especially following surgery and it does not interfere with platelet or kidney functions. Diclofenac belongs to the category of NSAIDs and are used orally, rectally, and as deep intramuscular injection and not intravenously (Samal et al., 2014). It is being used conventionally for many years for post-operative pain relief and a potent cyclooxygenase inhibitor. However, the associated side effects of this NSAID include peptic ulcer disease, gastrointestinal hemorrhage, renal dysfunction, altered liver function and platelet dysfunction (Kamtane et al., 2015). Pain measurement is usually difficult because pain is qualitative and subjective variable rather quantitative and objective variable. Moreover, pain is experienced differently under many conditions be it individual's morals, culture, gender, age and the nature of surgery performed (Hardman, 2001). The simplest method of monitoring pain is through observation of the behavior of the patient like whether the patient can get up, sit or do their activities etc. Physiological measures such as heart rate and blood pressure may increase in the presence of pain. However, patient self-report is the most reliable and valid measure of pain in the clinical situation. Pain scale measures a patient's pain intensity or other features. By these scales individuals' subjective perception of pain can be ranked in number. Many types of pain scales are used and they function best for the patient's subjective feeling of the intensity of pain. Visual analogue scale (VAS) is contemplated as one of the best methods for pain measurement and has been used as a pain evaluating indicator. Operationally a VAS is usually a horizontal line, 100 mm or 10 cm in length, anchored by word descriptors at each end. Zero indicates no pain while ten indicates maximum pain experienced by the patient. The patient marks on the line at the point that they feel represents their state they undergo at current situation. The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks (Gould, 2001).

MATERIALS AND METHODS

This study was a prospective observational comparative study approved (IEC/TOMCHRC/036/15/16) by the Institutional Ethics Committee of The Oxford Medical College Hospital and Research Centre, Attibele, Bangalore. A total of 140 patients, who had undergone surgeries and received paracetamol or diclofenac as post-operative analgesics in the department of general surgery and OBG during 6 months period in the year 2015-2016 where selected. Patient consent was obtained and all the necessary and relevant data were collected from the medical records of patients using a standard case report form. The pain ratings of the patients were taken by visual analogue scale and adverse drug reaction monitored using Naranjo adverse drug reaction probability scale (Naranjo et al., 1987). All post operative patients of age above 18 years and on single analgesic therapy receiving paracetamol or diclofenac were included for the study. American Society of Anesthesia (ASA) Grade III and above and renal or hepatic disorder patients were excluded according to exclusion criteria. The mean and standard deviation of the study population were calculated. All the cases were categorized based on gender and their ratio was determined. Data Analysis was performed by using Grapad InStat 3 software. 'P value' less than 0.05 were considered to be statistically significant. The comparison of pain score was carried out by using unpaired t-test.

RESULTS

One hundred and forty patients were enrolled; 87 patients from general surgery wards and 56 patients from obstetrics and gynecology wards were included in the study. The patients were divided into 2 groups, Group P and Group D. Patients of Group P received paracetamol and Group D received diclofenac.

Gender wise distribution of patients

The table 1 shows that the overall gender distribution of the patients were found to be 41(29%) for males and 99(71%) for females. It shows that the majority of the patients were female, 71%.

Patients receiving paracetamol and diclofenac

Figure 1 shows that out of 41 male patients, 10 % (4) received paracetamol and 90% (37) receives diclofenac for reliving their pain. Figure 2 shows that out of 99 female patients 67% (66) received paracetamol and 33% (33) received diclofenac for their pain.

Visual analogue scale (VAS) Score

The mean VAS score for pain assessment were given in the table 2. We observed the VAS score of patients for

Table 1: Gender Distribution of Patients

Gender Distribution	No. Of Patients (n=140)	Percentage (%)	P value	Significance
Male	41	29	0.18	NS
Female	99	71	0.2	NS

Table 2: Comparison for the Mean VAS Score

Time intervel	GROUP D MEAN VAS SCORE ± SD	GROUP P MEAN VAS SCORE ± SD	P VALUE
Day 1	6.21±1.24	6.98±1.07	0.0001
DAY 2	5.29±1.27	5.99±1.04	0.0005
DAY 3	4.27±1.29	4.91±1.16	0.0024
DAY 4	3.29±1.27	3.81±1.19	0.0136
DAY 5	2.09±1.05	2.6±1.11	0.0060

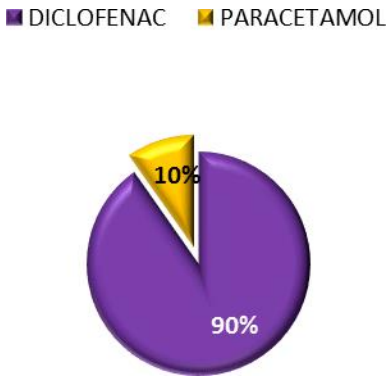

Figure 1: Male patients receiving paracetamol and diclofenac

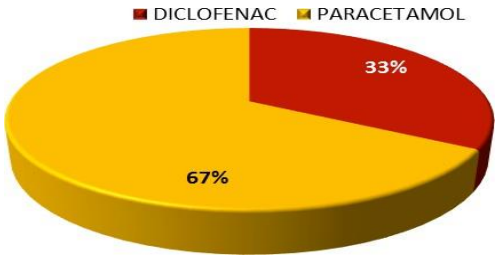

Figure 2: Female patients receiving paracetamol and diclofenac

Table 3: Types of Surgery

Surgeries	GROUP D		GROUP P	
	No.of cases	Percentage (%)	No.of cases	Percentage (%)
Appendectomy	19	27.143	2	2.85
Gynecological surgeries	12	17.14	48	68.57
Hemmorrhoidectomy	7	10.00	1	1.43
Debridement	7	10.00	5	7.14
Sphincterotomy	4	5.71	2	2.85
Hernioplasty	4	5.71	4	5.71
Cholecystectomy	3	4.28	1	1.43
Others	14	20.00	7	10.00

Table 4: ASA grade wise distribution

GROUP	ASA I	Percentage (%)	ASA II	Percentage (%)
Paracetamol	40	57.14	30	42.85
Diclofenac	49	70	21	30

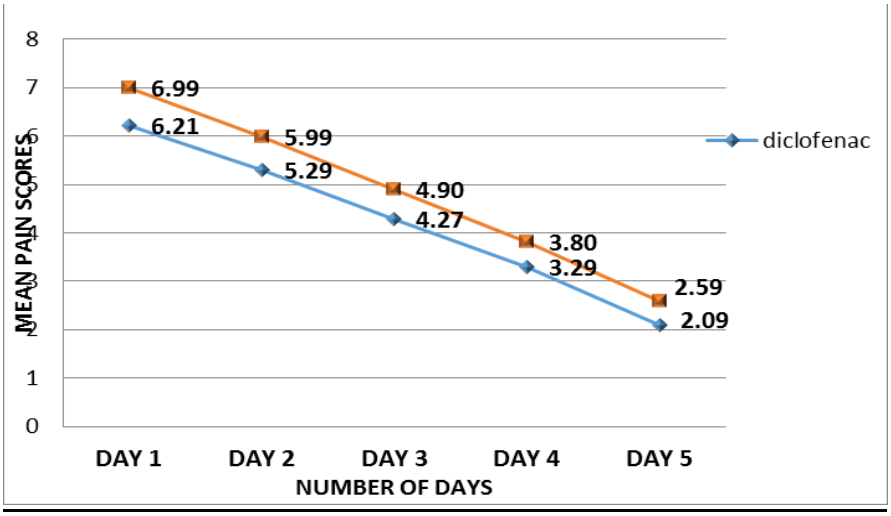

Figure 3: Mean Vas Score on Different Days

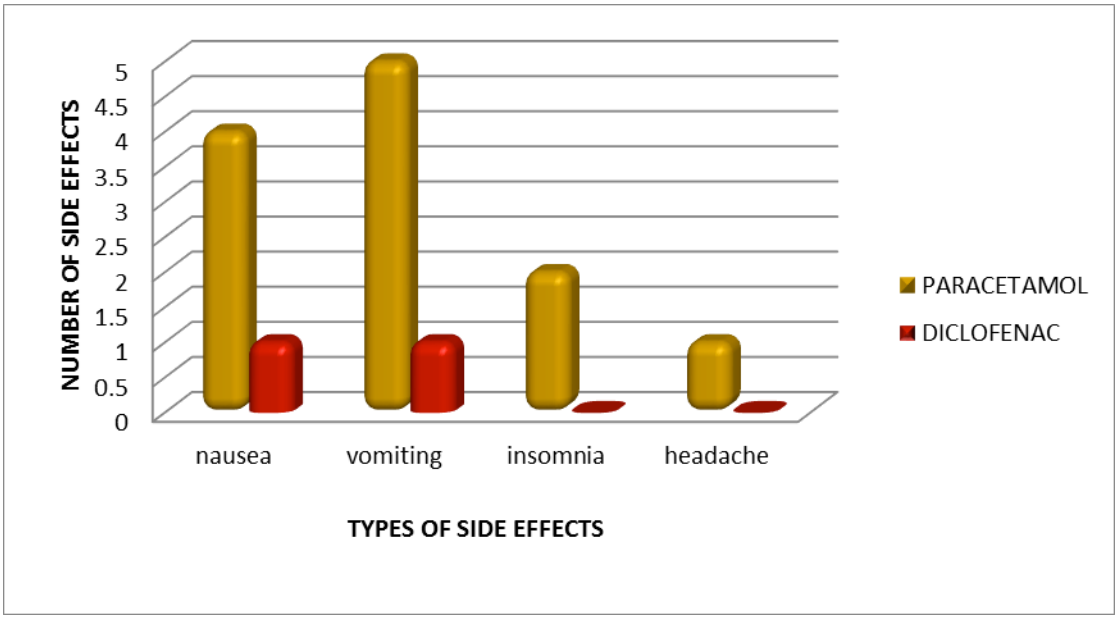

Figure 4: Side effects of Paracetamol and Diclofenac

5 days after surgery where the difference in VAS score was significant. The mean VAS score at day 5 were 2.09 (±1.05) in Group D and 2.6 (± 1.11) in Group P. There was a higher VAS score in Group P compared to Group D and difference were statistically significant (*p* value <0.05). The figure 3 shows a gradual decrease in mean VAS score in Group D.

Types of Surgeries

The table 3 showing types of surgeries done in patients. The majority of patients were undergone gynecological surgeries (68.57%) in paracetamol group and appendectomy (27.14%) in diclofenac group.

American Society of Anesthesia (ASA)

The table 4 shows the ASA grade wise distribution of patients. It is showing that 57.14% (40) patients fell under ASA grade I and 42.8 % (30) patients under Grade II in Group P. Where as in Group D, 70% (49) patients are under Grade I and 30% (21) patients are in Grade II.

Side Effects Different Groups

Side effects such as nausea, vomiting, insomnia and headache occurred in a very small fraction of patients who have administered these drugs. Figure 4 shows the side effects in different groups. It was shown that out of 140 patients 14 patients are experienced with side effects. There were four patients experienced nausea in paracetamol group and one patient in diclofenac group. There were five patients reported vomiting in paracetamol group and one patient reported the same in diclofenac group. Only two insomnia cases and one headache case are reported in paracetamol group and no insomnia and headache reported in diclofenac group. The probability assessment was done using Naranjo's scale and all the adverse effect were found to fit in the category of "Possible".

DISCUSSION

Pain in the post operative period is an emotional and mental trauma with unpleasant physical experience. It is triggered by surgery and is often associated with autonomic, endocrine metabolic, physiological and behavioral response. Inadequate pain management leads to delayed mobilization and longer duration of stay in the hospital (Paul et al., 2015). Non-opioid analgesics are used worldwide as it reduces the opioid induced side effects (Pal et al., 2014). This was a prospective observational study to compare the effect of intravenous paracetamol and intramuscular diclofenac. The comparison of drugs was done post operatively which was similar to other studies (Taneja et al., 2015) who conducted a comparative study on the effect of paracetamol, diclofenac in post-operative care. But the study contradicts with the some studies (Goel et al., 2013) who conducted the pre-emptive analgesia of paracetamol and diclofenac. The number of males enrolled in the study based on the inclusion criteria was 29% while the females were 71% which is similar to study conducted by Debashish Paul. The males were 33.33% and females were 66.66% .Whereas in the study the males were high 54% and females were 46% which was similar to other study conducted by Zahld Ahamad. In our study we found that the VAS score was high in the paracetamol group than the diclofenac group which was similar to some studies (Paul et al., 2014). In our study the patients under ASA I administering paracetamol was 21 and diclofenac was 49. Whereas the patients under ASA II administered paracetamol was 30 and diclofenac was 40. In a similar study conducted by Debashish Paul showed that the patients under ASA I administering paracetamol was 20 and diclofenac was 22. Whereas the patients under ASA II administering paracetamol was 10 and diclofenac was 08. Side effects such as nausea, vomiting, insomnia and headache occurred in a very small fraction of patients who were administered these drugs. In our study we found that, out of 140 patients 14 patients experienced side effects. There were four patients experienced nausea in paracetamol group compared to one patient in diclofenac group. Whereas 05 patients reported vomiting in group P and one in patient group D. There were only two insomnia cases and only headache were reported in paracetamol group and no insomnia and headache reported in diclofenac group. In a similar study conducted by some the incidence of side effects and complications were more in paracetamol group compared to diclofenac group (Bhavsar et al., 2014).

CONCLUSION

Post-operative analgesia is the keystone to a successful recovery from any surgery. Among the various agents tried so far, each have brought with it, their own advantages and disadvantages. From the different parameters compared and outlined in our study, following conclusions could be drawn that IV paracetamol and IM diclofenac tends to offer adequate post-operative analgesia. Nonetheless from our study, it was established that IM diclofenac appears to be a superior post-operative analgesic compared to IV paracetamol with lesser side effect. Hence, IM diclofenac is safer in the post-operative period, which leads to lesser duration of hospitalization and hence earlier discharge.

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REFERENCE

Bhavsar, M., Kheskani, D., Shah, P., Tyagi, A. and Upadhyaya, R. (2015) 'A comparative evaluation of per rectal diclofenac sodium and paracetamol for postoperative analgesia in case of hydrocephalus', *International Journal of Medical Science and Public Health*, 4(3), p. 373.

Cançado, T.O., Omais, M., Ashmawi, H.A. and Torres, M.L.A. (2012) 'Chronic pain after Cesarean section. Influence of anesthetic/surgical technique and Post-operative Analgesia', *Brazilian Journal of Anesthesiology*, 62(6), pp. 762–774. doi: 10.1016/s0034-7094(12)70177-0.

Dawoodi, I. and Khety, Z. (2014) 'Comparative Efficacy and Safety Study of Analgesic Effect of Fentanyl I.V. and Paracetamol I.V. in Postoperative Patients in Multidisciplinary Hospital.', *Research Journal of Pharmaceutical, Biological and Chemical Sciences*, 5(5), pp. 664–668.

Goel, P., Kothari, S., Gupta, N., Kumar, A. and Chaturvedi, S.K. (2013) 'Pre emptive analgesia with iv paracetamol and iv diclofenac sodium in patients undergoing various surgical procedures: a comparative study', *International Journal of Biological & Medical Research*, 4(3), pp. 3294–3300.

Gould, D. (2001) *Visual analogue Scale*. Available at: http://www.blackwellpublishing.com/specialarticles/jcn_10_706.pdf (Accessed: 22 November 2015).

Hardman, J. and Limbird, L. (2001) *Goodman and Gilmane's The pharmacological basis of therapeutics*. 10th edn. Dallas: McGraw hill.

Kamtane, R.A., D, S., G, P. and Y, S. (2015) 'safety and efficacy of tramadol compared to diclofenac in relieving postoperative pain', *Journal of Evidence Based Medicine and Healthcare*, 2(21), pp. 3103–3110.

Moonesinghe, S.R., Mythen, M.G. and Grocott, M.P.W. (2011) 'High-risk surgery', *Anesthesia & Analgesia*, 112(4), pp. 891–901. doi: 10.1213/ane.0b013e3181e1655b.

Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, Janecek E, Domecq C, Greenblatt DJ. *A method for estimating the probability of adverse drug reactions.*, 30 ed.: 1987.

Pal, A., Mukhopadhyay, P., Sanyal, P., Dasgupta, S., Das, S. and Biswas, J. (2014) 'Diclofenac is more effective for post-operative analgesia in patients undergoing lower abdominal gynecological surgeries: A comparative study', *Anesthesia: Essays and Researches*, 8(2), p. 192.

Paul, D., Jacob, M. and Kulkarni, S.N. (2015) 'Comparative evaluation of efficacy of intravenous paracetamol and intravenous diclofenac as post-operative analgesia in laparoscopic cholecystectomy', *International Journal of Biomedical Research*, 6(7), p. 482.

Samal, S., John, E., Chandrasekar, L.J., Nithianandam, S. and Jena, S.K. (2013) 'A comparative study of intravenous Diclofenac and combination of intravenous Paracetamol with intravenous Diclofenac for the Postoperative pain management', *The Internet Journal of Anesthesiology*, 32(2),accessed 12 September 2016, http://ispub.com/IJA/32/2/14548

Sodhi, V. and Fernando, R. (2003) *Clinical Surgery In General*. Edited by R M Kirk and W J Ribbans. 4th edn. Elsevier

SSM (2015) Available at: http://surgicalspecialistsmn.com/how-to-manage-and-control-pain-after-surgery (Accessed: 24 February 2016).

Taneja, A., Vidhushi, Kaur, T. and Sood, I.V. (2015) 'Comparative Study on The Effect of Paracetamol, Diclofenac and their Combination in Post Operative Pain Relief of Cesarean Section', *JK SCIENCE*, 17(1), pp. 30–32.