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"Comparison of Safety and Efficacy of 5mg Buprenorphine Transdermal Patch and 50mg Tramadol Injection For Post Operative Pain Relief After Hemiarthroplasty In A Tertiary Care Hospital In South India"

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ABSTRACT
OBJECTIVES:1. To compare safety and efficacy of 50mg intravenous tramadol and 5mg buprenorphine transdermal patch for postoperative pain relief after hemiarthroplasty
2.To identify side effects of injection tramadol and buprenorphine transdermal patch
METHODS: A prospective observational study was directed on 72 patients during a study period of 6 months. Detailed literature review was conducted by using tertiary, secondary, primary resources. All the required study materials like informed consent document, patient information sheet and data entry form were designed. The study was conducted only after getting endorsement from the Institutional Ethical Committee(IEC). 72 patients, who met the inclusion criteria, were enrolled in the study. Data was gathered on the designed data entry form. Comparison was done to assess postoperative pain relief after using intravenous tramadol and buprenorphine transdermal patch.
RESULT: When comparing intravenous tramadol and buprenorphine group. Side effects like constipation, vomiting and breathing difficulty is more prominent in tramadol group. Out of 36 patients in Buprenorphine group only 3 has to use rescue analgesic whereas in tramadol group 8 patients has to use rescue analgesic.
CONCLUSION: Buprenorphine transdermal patch is more effective in case of post operative pain relief
KEY WORDS: Tramadol, Buprenorphine

I. INTRODUCTION

Hemiarthroplasty involves replacing femoral head with a prosthesis retaining the natural acetabulum and acetabular cartilage. In total hip replacement acetabulum is replaced along with femoral head.Complications of hemi arthroplasty include dislocation ,infection, acetabular wear etc.Femoral neck damage is common in elderly.Hemiarthroplasty is associated with severe to moderate postoperative pain.Effective postoperative pain relief is a major challenge in elderly population.
Injection tramadol and buprenorphine transdermal patch are common analgesics used for postoperative pain relief after hemiarthroplasty.Postoperative pain relief is assessed with the help of visual analogue scale.

Tramadol

- It functions as both a central opiate agonist and a reuptake inhibitor of serotonin and norepinephrine in the central nervous system.It is a mu receptor agonistIt is given orally, Intravenously, rectally, sustained release and in solutions for IM/IV administration
- It is used for postoperative pain, labor pain, cancer pain, treatment for osteoarthritic pain, for the relief of acute trauma etc.Tramadol is able to cross placental barrier.Liver performs the metabolism of tramadol by demethylation and conjugation process .
- 90% of tramadol and it metabolites eliminate through kidneys and 10% eliminate through faecus.

Buprenorphine

Buprenorphine is a semisynthetic derivative of thebaine.It act as a partial mu agonist and kappa antagonist.It is administered as transdermal patch.

- Buprenorphine is lipid soluble and active transdermally.
- Buprenorphine is tightly bound to plasma protein.
- 5mg buprenorphine transdermal patch releases 5mcg drug in a continuous manner.
- Buprenorphine is used for post operative pain, chronic pain and cancer pain.
- Buprenorphine transdermal patch is applied to dry, non hairy area of the body
- ✓ Most of the studies are based on comparisons of tablet tramadol and buprenorphine

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transdermal patches .This study is intended to compare intravenous tramadol and buprenorphine transdermal patch.

II. MATERIALS AND METHODS

A prospective observational study was conducted over a period of six month , from December 2022 to June 2023 , using 72 hemiarthroplasty patients obtained from the department of orthopaedics department KMCT MEDICAL COLLEGE HOSPITAL Manassery . Ethical approval was obtained from the institutional ethics committee through letter number 132 dated 15/12/2022.

INCLUSION CRITERIA

- Patients with age more than 60 after hemiarthroplasty
- Patients who are willing to participate in study

EXCLUSION CRITETERIA

- Psychiatric patients
- Patient who are not willing to participate in study

PROCEDURE

This prospective observational comparative study titled:
"COMPARISON OF SAFETY AND EFFICACY OF 5mg BUPRENORPHINE TRANSDERMAL PATCH AND 50mg. TRAMADOL INJECTION FOR POST OPERATIVE PAIN RELIEF AFTER HEMIARTHROPLASTY IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA" "was conducted on 72 patients after hemiarthroplasty. Post-operative patients in orthopedic department are identified and satisfying inclusion criteria will be selected.

- ❖ Patient details are entered in data collection form.
- ❖ Categorize the patients as those using tramadol injection and buprenorphine transdermal patch. Educate patient and bystander about how to use visual analogue scale.
- ❖ Rescue analgesic may be given if necessary.

STATISTICAL ANALYSIS

The collected data was analysed using jamovi software version 2.3 and R Core team (R:A language and environment for statistical computing version 4.1). Mean, median, standard deviation were calculated for metric parameters. Paired t test, independent t test and chi square test were used for the analysis. A p-value less than 0.05 was considered significant.

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III. RESULTS

CATERGORISATION BASED ON AGE

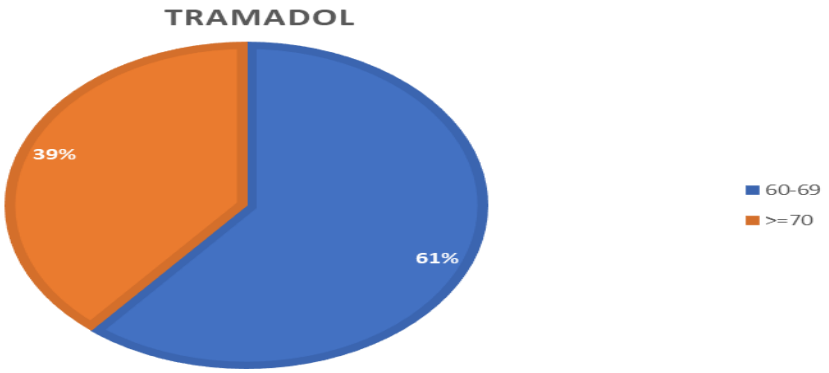

FIGURE NUMBER:1

PIE CHART BASED ON AGE OF TRAMADOL GROUP
DISCUSSION: Maximum population was found in age group 60-69

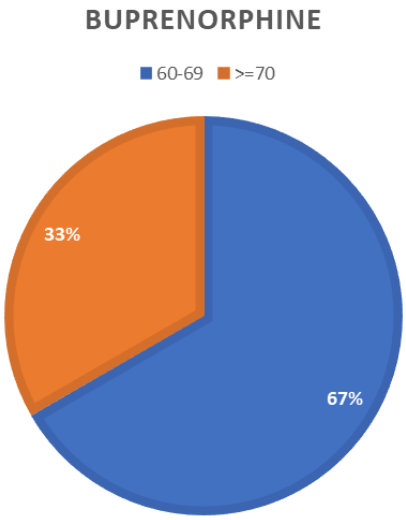

FIGURE NUMBER:2

PIE CHART BASED ON AGE OF BUPRENORPHINE GROUP
DISCUSSION: Maximum population was found in age group of 60 - 69

CATEGORISATON BASED ON GENDER

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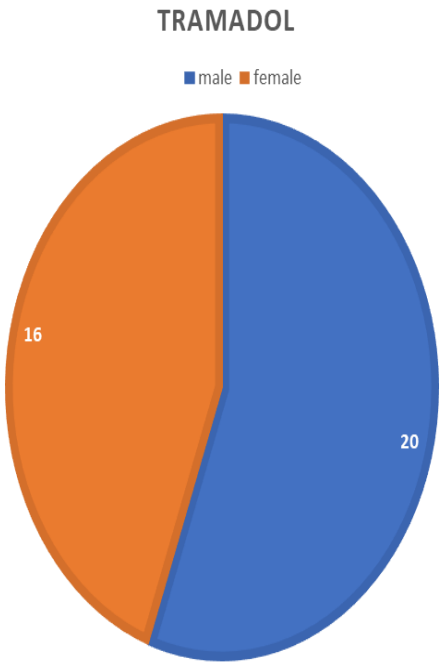

FIGURE NUMBER:3

Gender distribution in tramadol group
DISCUSSION :Maximum population was distributed in male group

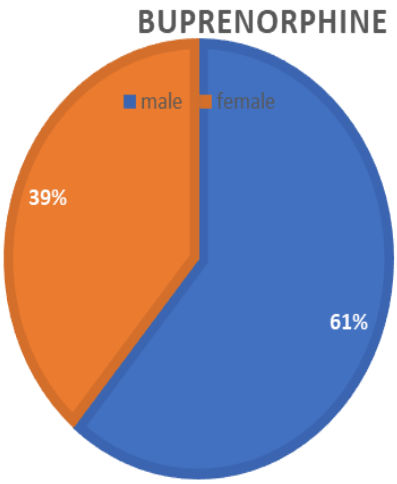

FIGURE NUMBER:4

GENDER DISTRIBUTION IN MALE GROUP

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DISCUSSION: Maximum population was distributed in male group

CATEGORISATION BASED ON SIDE EFFECT

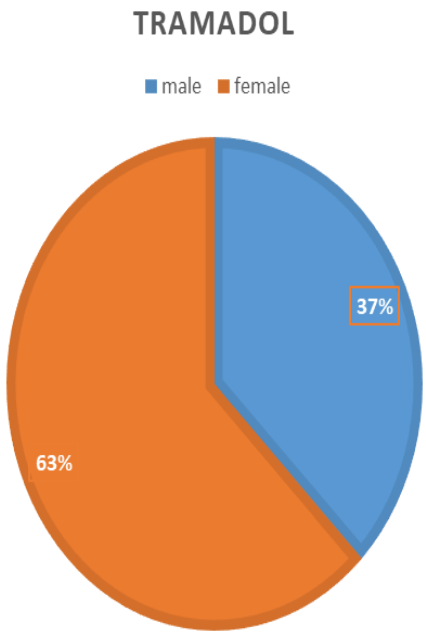

FIGURE NUMBER:5

Side effect in tramadol group
DISCUSSION: Maximum side effect was found in female group

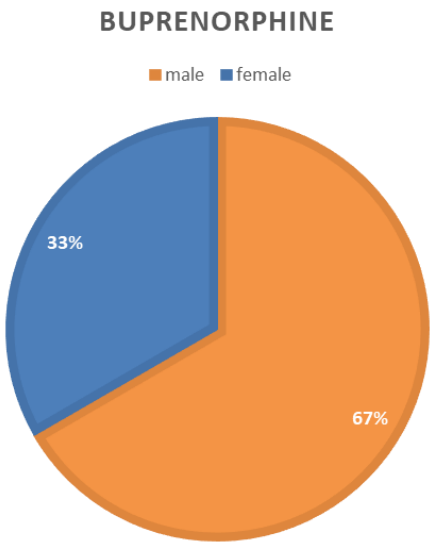

FIGURE NUMBER:6

Side effect in buprenorphine group
DISCUSSION: Maximum side effect was found in male group

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TREATMENT CHART	MALE	FEMALE
TRAMADOL	3	5
BUPRENORPHINE	2	1

TABLE NUMBER:1

In tramadol group 4 patients had constipation. In buprenorphine group 2 patients had constipation. Most common side effect is constipation. In buprenorphine group one patient had breathing difficulty.

CATEGORISATIONBASEDONRESCUEANALGESIC

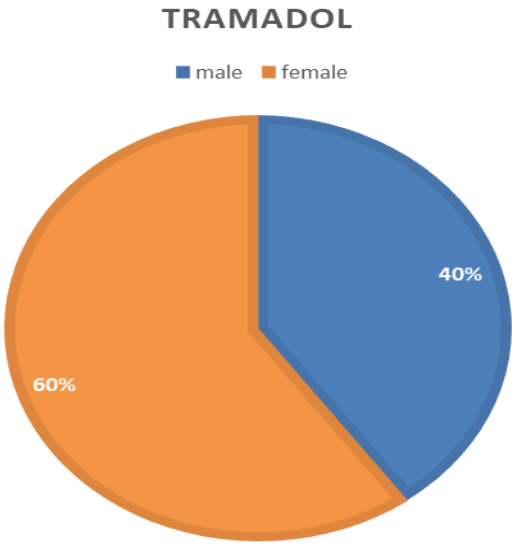

FIGURE NUMBER:7

RESCUE ANALGESIC IN TRAMADOL GROUP

DISCUSSION: Rescue analgesics are more used in tramadol group

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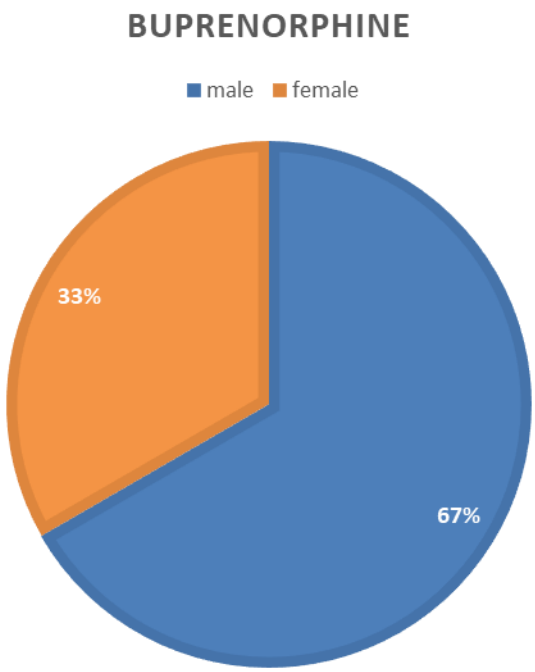

FIGURE NUMBER:8

RESCUE ANALGESIC IN BUPRENORPHINE GROUP

NUMBER OF RESCUE ANALGESICS USED IN TRAMADOL AND BUPRENORPHINE

TREATMENT CHART	MALE	FEMALE
TRAMADOL	2	3
BUPRENORPHINE	2	1

TABLE NUMBER:2

There is no significant change in the pain score at the first and third visits. On the second visit there is a significant change the pain score is low in the buprenorphine group therefore we can interpret the buprenorphine transdermal patch to be safer and more effective than intravenous tramadol. Both provide pain relief however side effects and the need for rescue analgesics are more frequent in the tramadol group. P value shows significant change in second visit only

	TREATMENT GROUP	MEAN	MEDIAN	STANDARD DEVIATION	STANDARD ERROR	P VALUE
AGE	MALE	69.42	68.50	6.349	1.058	
	FEMALE	67.83	67.50	5.464	.911	0.261
FIRST VISIT	TRAMADOL	8.33	8.0	.717	.120	
	BUPRENOPHINE	8.42	8	.604	.101	0.595
SECOND VISIT	TRAMADOL	5.75	6	.806	.134	
	BUPRENORPINE	5.39	5.5	.728	.121	0.050
THIRD	TRAMADOL	2.42	2.5	.732	.122	

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VISIT	BUPRENORPHINE	2.28	2	.779	.130	0.438

TABLE NUMBER:3

IV. DISCUSSION

Hemiarthroplasty is a process of replacing the femoral head with aprosthetic bone while the natural acetabulum .It is usually performed when the hip neck is damaged. Femoral neck damage is common in elderly patients.In elderly patients, damage to the femoral neck is common due to osteoarthritis or wear and tear over time.Hemiarthroplasty is suitable for damage to the femur.Successfulhemiarthroplasty is achieved through postoperative pain control. Postoperative pain management is a major challenge in hemiarthroplasty. Postoperative complications can affect the overall outcome of the surgery.It is important to choose the most effective pain reliever for postoperative pain relief.Intravenous Tramadol and Buprenophine transdermal patch are two opiod analgesics used for postoperative pain relief.All patients meeting the inclusion criteria participated in the study. Side effects such as constipation, vomiting,nausea,difficulty breathing have been identified. Constipation more prominent.Side effects are more observed in the tramadol group.

If uncontrolled pain occurs even after administration of these painkillers, an emergency painkiller is used.In our study paracetamol is the emergency analgesics.A visual analogue is used to assess pain relief. In our injection study treatment group, Tramadol used 5 rescue pain killers, while the Buprenorphine group used 3 rescue painkillers.Pain is assessed over 3 visitors.There is no significant difference in the VAS score at the first and third visit between two treatment groups .There is a significant differences in the second visit assessment between the 2 treatment groups.The pain score is low in the Buprenorphine group . From this study, we observed that Buprenorphine transdermal patch is safer and more effective than intravenous tramadol for postoperative pain relief after hemiarthroplasty.A similar study conducted by Sanjay Londhe et al.., was conducted to compare the safety and efficacy of aTDP patch to conventional analgesics after the arthropastysurgery.They compared Buprenorphine transdermal patch with conventional analgesic. The conventional analgesic was the combination of tramadol and paracetamol.In this study ,the Buprenorphine patch was found to be more effective.

LIMITATIONS

- The number of patients was limited. Potentially large samples was required for the study to get more significant results.
- Some patients had trouble understanding VAS.
- Study is based on tertiary Centre and thus the results may not be generalizable to all patients in the community.
- There were only a small number of cited published papers on study of postoperative pain relief after orthopedic surgery.

V. CONCLUSION

In this study, it is concluded that buprenorphine transdermal patch is better suited for postoperative pain relief in hemiarthroplasty. Both tramadol and buprenorphine are effective in relieving postoperative pain. However,intravenous tramadol is associated with side effects such as constipation, difficulty breathing, and vomiting. A common side effect associated with intravenous tramadol therapy is constipation. Of the 36 patients in the buprenorphine group, only 3 used a rescue analgesic, whereas in the tramadol group 5 patients used a rescue Analgesic.

ACKNOWLEDGEMENT

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