Original Research Article

A COMPARATIVE CLINICAL STUDY OF INTRATHECAL CLONIDINE AND DEXMEDETOMIDINE ADDED WITH BUPIVACAINE FOR POST-OPERATIVE ANALGESIA IN GYNAECOLOGICAL SURGERIES.

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ABSTRACT: “A comparative clinical study of intrathecal Clonidine and Dexmedetomidine added with Bupivacaine for post-operative analgesia in gynaecological surgeries.”

AIMS AND OBJECTIVES: The present study was carried out in 200 patients of ASA grade I/II, posted for gynaecological surgeries from March 2023 to Jan 2024 at People’s College of Medical Sciences and Research Centre, Bhopal with aims of:

- To determine the onset, duration and regression of sensory blockade with Clonidine and Dexmedetomidine.
- To determine the onset, duration and regression of motor blockade with Clonidine and Dexmedetomidine.
- To observe the haemodynamic changes with Clonidine and Dexmedetomidine.
- To determine and compare the duration of effective postoperative analgesia.
- To assess any complication or adverse effects with Clonidine and Dexmedetomidine.

METHODOLOGY: Patients were randomly divided into two groups:

1. Group C (n=100): (Clonidine group): 15 mg of 0.5% Bupivacaine (H) + Inj. Clonidine 30 µg,
2. Group D (n=100): (Dexmedetomidine group): 15 mg of 0.5% Bupivacaine (H) + Inj. Dexmedetomidine 10 µg,

STATISTICAL ANALYSIS: Data collected were analyzed and expressed as mean and standard deviation or numbers and percentages as applicable. Comparison between two groups was done using unpaired students “t” test for quantitative data and chi square test for qualitative data. P value < 0.05 is considered statistically significant.

CONCLUSION: Dexmedetomidine in the dose of 10 µg added to 15 mg Bupivacaine in subarachnoid block for gynaecological surgeries provides comparable onset for sensory and motor blockade but significantly prolonged duration as compared to 30 µg of Clonidine. Longer duration of postoperative analgesia with Dexmedetomidine makes it superior to Clonidine in respect to postoperative analgesia. Both the drugs produce desirable level of intraoperative and postoperative sedation, stable haemodynamics and minimal side effects.
KEYWORDS: Subarachnoid block, Bupivacaine, Clonidine, Dexmedetomidine, gynaecological surgeries.

1. INTRODUCTION:

“Pain is a perfect misery, worst of all evils and when excessive overturns all patience.”-Paradise lost by Milton. The International Association for the Study of Pain defines pain as “… an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”

Surgical trauma is real and severe tissue damage and surgical pain is a universal phenomenon which is aggravated by associated muscle spasm and visceral distention. By rendering the patient pain free during surgery, anaesthesiologist have succeeded to a considerable extent, but once the luxury of pain free surgery is over, the patient has to face misery of post-operative pain.

Relief of operative as well as post-operative pain is important because it interferes with respiration, bowel movements and micturition.

Neuraxial block was first introduced into clinical practice by August Bier in 1898 and ever since, neuraxial block has been the main stay of anaesthesia for surgery of lower abdomen and lower extremities.

In recent times, the increasing use of subarachnoid narcotics for post-operative analgesia promises of new venue in this field.

The main stay of post-operative pain relief is still the use of potent analgesics in the post-operative period. It has proved difficult to find a drug which is a great improvement over narcotics. Subarachnoid block is a popular technique for gynaecological surgeries. Subarachnoid block has the advantage of simplicity of technique, rapid onset of action and reliability in producing uniform sensory and motor blockade. Its main disadvantage relates to its limited duration of action and hence, lack of long lasting post-operative analgesia. To overcome this problem, administration of local anaesthetics in combination with different adjuvants is an excellent technique which not only relieves postoperative pain but also refines the quality of sensory and motor blockade of subarachnoid block and hence, acts as synergistic to local anaesthetics with lower local anaesthetic requirement, decreased side effect and excellent post-operative analgesia.

Most of the clinical studies about α2 receptor agonists are related to the clonidine. Clonidine, α2 adrenergic agonist, potentiates the effect of local anaesthetics and allows decrease in the required doses.

Clonidine is a partial α2 adrenergic agonist used intrathecally with well-established efficacy and safety profile with effective prolongation of both motor and sensory spinal blockade.

Dexmedetomidine, another member of α2 agonist’s family, is recently being introduced and is approved as an intravenous sedative and co-analgesic drug.

It has eight times higher affinity for α2 receptors than clonidine. In previous clinical studies, intravenous dexmedetomidine resulted in significant opioid sparing effect. Analgesic properties were found when intrathecal or epidural dexmedetomidine was used.
Dexmedetomidine is an effective and safe adjuvant to local anaesthetics in subarachnoid block.

AIMS AND OBJECTIVES
The present study was carried out in 200 patients of ASA grade I/II, posted for gynaecological surgeries from March 2023 to Jan 2024 at People’s College of Medical Sciences And Research Centre, Bhopal with aims of:

- To determine the onset, duration and regression of sensory blockade with Clonidine and Dexmedetomidine.
- To determine the onset, duration and regression of motor blockade with Clonidine and Dexmedetomidine.
- To observe the haemodynamic changes with Clonidine and Dexmedetomidine.
- To determine and compare the duration of effective postoperative analgesia.
- To assess any complication or adverse effects with Clonidine and Dexmedetomidine.

2. MATERIAL AND METHODS

After approval from the Institutional Ethics Committee (Registration no. ECR/519/Inst/MP/2014/RR-20) and CTRI/2023/03/051196 and informed written consent from patients, this present study was carried out in the Department of Anaesthesiology, People’s College of Medical Sciences And Research Centre, Bhopal.

Two hundred patients, aged 18-50 years of ASA Physical status I and II, scheduled for elective gynaecological surgeries were enrolled in this study.

All the patients were subjected to detailed pre-anaesthetic evaluation with clinical history and systemic examination. Routine investigations like Haemogram, Random blood sugar, renal profile, urine examination, X-ray chest and ECG were done.

INCLUSION CRITERIA:
- Informed written consent for participation in study.
- Age: 18-50 years.
- Patients posted for gynaecological surgeries.
- ASA physical status I and II.

EXCLUSION CRITERIA:
- Contraindication to subarachnoid block.
- Allergy to local anaesthetic or study drug.
- Uncontrolled or labile hypertension.
- Patients taking any analgesics, sedative or antihypertensive drugs.
- Neurological disorders.
- Psychiatric disorders.
- Uncooperative patients.
Every patient was informed in detail regarding nature and purpose of the study and was explained 0-10 point visual analogue scale (VAS) on a sheet of paper, where (0) labelled as (no pain) and (10) as (worst possible pain). Patients were randomly divided into two groups:
1. Group C (n=100): (Clonidine group): 15 mg of 0.5% Bupivacaine (H) + Inj. Clonidine 30 µg.
2. Group D (n=100): (Dexmedetomidine group): 15 mg of 0.5% Bupivacaine (H) + Inj. Dexmedetomidine 10 µg.
In the operation theatre, peripheral venous access was secured on hand of patient with 18 G cannula and preloading with Inj. Ringer Lactate 10-15 ml/kg was initiated

**EQUIPMENTS:**
- One L.P. Needle 25GA.
- 2 ml and 5 ml syringe each.
- One small bowl.
- Sponging holding forcep.
- Gauze pieces.
- Towel for draping.
- Betadine and spirit solutions.
All equipments necessary for resuscitation were kept at hand.

**DRUGS:**
- One ampoule of Bupivacaine 0.5% (H).
- One ampoule of Clonidine (150 µg/ml).
- One ampoule of Dexmedetomidine (100 µg/ml).

**STATISTICAL ANALYSIS:**
We included 100 patients per group.
Data collected were analyzed and expressed as mean and standard deviation or numbers and percentages as applicable. Comparison between two groups was done using unpaired students “t” test for quantitative data and chi square test for qualitative data. P value < 0.05 is considered statistically significant.
3. OBSERVATIONS AND RESULTS

SHOWING COMPARISON OF SENSORY CHARACTERISTICS OF SUBARACHNOID BLOCK BETWEEN TWO GROUPS -

SHOWING COMPARISON OF MOTOR CHARACTERISTICS OF SUBARACHNOID BLOCK BETWEEN TWO GROUPS -

SHOWING STATISTICAL ANALYSIS OF PULSE RATE (PER/MIN) BETWEEN TWO GROUPS -

Changes in Mean Arterial Pressure between two groups -
SHOWING STATISTICAL ANALYSIS OF SpO₂ (%) BETWEEN TWO GROUPS

Sedation score between two groups

Visual Analogue Scale and time of first rescue analgesic required in two groups

1314
Duration of effective analgesia between two groups-

![Chart showing duration of effective analgesia between two groups]

**SHOWING COMPLICATIONS IN TWO GROUPS-**

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group C</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients</td>
<td>%</td>
</tr>
<tr>
<td>Hypotension</td>
<td>3</td>
<td>06%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>3</td>
<td>06%</td>
</tr>
<tr>
<td>Nausea-Vomiting</td>
<td>4</td>
<td>08%</td>
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<tr>
<td>Headache</td>
<td>0</td>
<td>00%</td>
</tr>
<tr>
<td>Respiratory depression</td>
<td>0</td>
<td>00%</td>
</tr>
<tr>
<td>Neurological complication</td>
<td>0</td>
<td>00%</td>
</tr>
</tbody>
</table>

4. **DISCUSSION**

- Dexmedetomidine hydrochloride, a newer agent within the class of $\alpha_2$ adrenoceptor agonist, delivers clinically effective sedation within analgesic property for use in intensive care unit setting. Additionally, it has an ability to eliminate or reduce the need for other analgesic medications. There is no evidence of respiratory depression with Dexmedetomidine. Because of its selective $\alpha_2$ receptor activity, use of Dexmedetomidine has modest and predictable haemodynamic effects, making it a popular sedative and analgesic drug in intensive care unit.
In conclusion, Dexmedetomidine in the dose of 10 µg added to 15 mg Bupivacaine in subarachnoid block for gynaecological surgeries provides comparable onset for sensory and motor blockade but significantly prolonged duration as compared to 30 µg of Clonidine. Longer duration of postoperative analgesia with Dexmedetomidine makes it superior to Clonidine in respect to postoperative analgesia. Both the drugs produce desirable level of intraoperative and postoperative sedation, stable haemodynamics and minimal side effects.

5. REFERENCES

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