A Double-Blind Randomized Control Trial to Compare the Effect of Varying Doses of Intrathecal Fentanyl on Clinical Efficacy and Side Effects in Parturients Undergoing Cesarean Section

SCIENCE

Clinical Research

Key Take-Away:

The present study has indicated the use of 10 or 15 µg of intrathecal fentanyl with 10 mg of bupivacaine in patients undergoing a cesarean section. The combination of 10 or 15 µg of intrathecal fentanyl with 10 mg of bupivacaine can be helpful in providing adequate surgical anaesthesia and analgesia with a lower incidence of side effects.

Bupivacaine is the frequently used anaesthetics for the subarachnoid block in parturients undergoing the cesarean section. It is noticed that intrathecal bupivacaine alone is inadequate to provide entire anaesthesia. Therefore to improve the duration and quality of subarachnoid block, surgeons commonly add opioids such as fentanyl.

It is reported that intrathecal fentanyl is associated with the number of side effects such as pruritus, nausea/vomiting, and respiratory depression. The appropriate and safe dose of fentanyl is still unclear.

Previous studies assessed the adequate doses of intrathecal fentanyl for clinical efficacy but did not have sufficient ability to identify the differences in secondary outcome variables such as pruritus, respiratory depression, nausea, and vomiting. In this investigation, 25 µg of fentanyl is used with bupivacaine for spinal anaesthesia during cesarean section.

Rationale behind research

- The previous studies which assessed the varying doses of intrathecal fentanyl for clinical efficacy were not sufficient to detect the differences in secondary outcome variables such as pruritus, respiratory depression, nausea, and vomiting.
- Therefore, this study was conducted to compare 25 µg of intrathecal fentanyl with 10 and 15 µg doses in parturients undergoing a cesarean section.

Objective

To compare 25 µg intrathecal fentanyl with 10 and 15 µg doses in parturients undergoing cesarean section under spinal anaesthesia with intrathecal bupivacaine to assess:

1. The quality of surgical anaesthesia, onset, and duration of the block.
2. Occurrence of side effects such as pruritus, respiratory depression, nausea, and vomiting in parturients and low APGAR score in the newborns
3. Hemodynamic stability
4. The requirement of vasopressors.

Methods:

Study outcomes:

- **Primary outcomes:** Pain score, need for rescue analgesia, conversion to general anaesthesia, and complaints of the inadequacy of surgical anaesthesia by the surgeon**.**
- **Secondary outcomes:** The assessed side effects were pruritus, nausea, vomiting, dizziness, and decrease in saturation and respiratory rate.

In addition, neonatal APGAR score, patients' hemodynamics, need for vasopressors, onset and duration of sensory, and motor block was measured.

- **Time period:** NA

Results:

Outcomes

- **Baseline:** No significant differences observed at baseline
- **Study outcomes:**
- There was no statistically significant difference found in the quality of surgical anaesthesia, level of consciousness, the onset of sensory and motor block, pain scores and neonatal APGAR scores between the three groups (Fig:2)

- A significant difference was observed in the occurrence of side effects among all the three groups, both in the OR and RR.

Discussion

Conclusion

In the present study, there was no significant difference among the three groups in the quality of surgical anaesthesia. Most of the patients (95–96%) reached to a great level of surgical anaesthesia with all three doses of fentanyl, with only 6 (2.46%) requiring intravenous rescue analgesia and none requiring conversion to general anaesthesia. Previous studies have shown the significantly higher number of failed blocks at a dose of 7.5 µg. As per the survey conducted by Chu et al. all the patients receiving 12.5 and 15 µg of intrathecal fentanyl with 0.5% hyperbaric bupivacaine experienced excellent analgesia as compared to 7.5 µg of fentanyl.

Moreover, in a study conducted by Goel et al. it was found that the patients receiving 7.5 µg of fentanyl in combination with low-dose bupivacaine had a significantly higher number of failed blocks (27%) than those receiving 10 or 12.5 µg of fentanyl. Therefore, most of the researchers favour using doses of intrathecal fentanyl higher than 10 µg. In this study, the lowest dose of intrathecal fentanyl was 10 µg, and no difference in the anaesthesia was observed provided by 10µg dose and the higher doses of fentanyl (15 and 25 µg).Therefore, it can be deduced that increasing the dose of intrathecal fentanyl more than 10 µg

does not add to the quality of surgical anaesthesia.

The opioid is added to the local anaesthetic not only to improve the quality of surgical anaesthesia but also for the onset and duration of the block. Therefore, combining an opioid with a local anaesthetic may add local anaesthetic sparing effects and lead to a shorter onset time and prolonged duration for the sensory block. In this study, the time of achieving the sensory block of T5 and motor block was similar in all the three groups, indicating that it is the presence of opioid and not the dose of opioid that affects the onset of the block. However, it was observed that the duration of motor and sensory block increased with an increase in the dose of fentanyl.

The incidence of pruritus was found to be highest in the patients from Group 25 among all the study groups. Some studies have shown nonsignificant pruritus in patients receiving 25 µg and less of intrathecal fentanyl. One of the possible reasons might be that as none of these studies has measured pruritus as the main outcome. This study was designed with a sample size large enough to detect the differences in pruritus, respiratory depression, nausea, and vomiting.

The incidence of nausea was the highest in the patients from Group 25, while no difference was seen in the frequency of vomiting among the three groups. The high incidence of nausea observed in this study is not comparable to other studies, which showed either less or no differences. The higher incidence of nausea could be due to the variation in surgical technique, including uterine exteriorization in some patients, as well as variations in the level of anxiety among patients. APGAR score of the babies remained the same in all groups and also compatible with other studies.

In conclusion, out of all three examined doses of intrathecal fentanyl, 15µg determined as the safer and optimal dose used with 10 mg bupivacaine for cesarean section under spinal anaesthesia.

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Therapeutic, Fentanyl, Bupivacaine, Pain, Cesarean Section, Opioid, Local anesthetic, Prospective randomized double-blind study, Efficacy, Safety, Numeric Rating Scale (NRS), Neonatal