Intravenous Propofol as An Adjunct to Spinal Anesthesia to Provide Sedation- A Clinico-Epidemiological Study

Dr. Anil Kumar Gupta¹, Dr. Garima Singh², Dr. Pushpendra Singh Chahar³, Dr. Nitin Tiwari⁴*,
Dr. Tuhin Vashishth⁵

Abstract
Background: Regional anesthesia is becoming an increasingly important aspect of anesthetic practice. Propofol offers titratable sedation and rapid recovery compromising hemodynamic stability. This may prove to be an important clinical consideration for its use as an adjunct to spinal anesthesia. So, this study investigated the properties of propofol when given by intravenous infusion to provide sedation as an adjunct to spinal anesthesia.

Material and Methods: A prospective, clinical study was conducted among patients aged 18-40 years for elective surgery under spinal anesthesia. A total of 60 pregnant patients undergoing a C-Section with spinal anesthesia were randomly allocated into two groups. Patients in Group P (received a propofol infusion at a rate of 50 µg/kg/min), Inj. Hyperbaric Bupivacaine 0.5%, 2.5 cc (12.5 mg) intrathecally, and Group C (received 100 ml of isotonic solution), Inj. Hyperbaric Bupivacaine 0.5%, 2.5 cc (12.5 mg) intrathecally. The level of sedation was recorded every 5 minutes (Level 4 or 5) on a 5-point sedation score.

Results: The mean age group P was 27.2 +/- 6.6 years and group C was 30 +/- 7.3 years. The average duration of surgery was 60 ± 12.7 minutes, the anesthetic time for group P was 68.8 ± 2.7 and for the group, C was 68.0 ± 6.5 and statistically significant (p<0.05). Recovery was impressively rapid and patients regained full consciousness approximately 7.8 ± 2.4 in group P after the end of infusion and were free from minor postoperative sequelae than group C.

Conclusion: It has been concluded that intravenous propofol sedation as an adjunct to spinal anesthesia is associated with a lower incidence of postoperative complications & better compliance. Our findings should be confirmed in future prospective studies and more research trials are needed to find optimized doses for different ages, gender, and health status. The development of new modes of administration is a matter of interest and improved quality of sedation is much needed of the hour.

Keywords: intravenous propofol, Anesthetics, spinal anesthesia, Sedation

INTRODUCTION:
Regional anesthesia is becoming an increasingly important aspect of anesthetic practice. Its advantages include the avoidance of certain risks inherent in general anesthesia, particularly those of airway obstruction and pulmonary aspiration, the avoidance of operating theatre pollution, the provision of good postoperative analgesia, and the benefits of certain pre-existing medical conditions. [1] Light sedation with an intravenous agent is the method of choice to avoid the disadvantages of general anesthesia. However, to preserve the benefits of the local technique, recovery must be rapid and clear-headed, with freedom from minor postoperative sequelae. Propofol is commonly used as a sedative by infusion during regional anesthesia. [2] Although propofol offers titratable sedation and

*Corresponding Author: - Dr. Nitin Tiwari
Address: ⁴Assistant Professor, ASMC Firozabad, Uttar Pradesh. Email: doctor4unitin@gmail.com
¹Assistant Professor, ASMC Firozabad, Uttar Pradesh. Email: dranilgupta77@gmail.com
²Assistant Professor, S N Medical College, Agra, Uttar Pradesh. Email: drgarimasingh1982@gmail.com
³Senior Resident, S N Medical College, Agra, Uttar Pradesh. Email: drpushpendra12@gmail.com
⁵Professor and Head, ASMC Firozabad, Uttar Pradesh. Email: drtuhinv@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest
rapid recovery, it can compromise hemodynamic stability. This may prove to be an important clinical consideration for its use as an adjunct to spinal anesthesia, as hypotension is a frequent complication of sympathetic blockade. Propofol, the new emulsion formulation of di-isopropyl phenol, with its attractive pharmacokinetic profile would appear to be a logical agent to use in this manner. Previous studies with the Cremophor formulation showed that its use was associated with rapid recovery and freedom from postoperative side effects. [3, 4]

Indeed, many recent studies have shown that propofol, when given either by intermittent bolus or continuous infusion, is an excellent agent for providing light general anesthesia as an adjunct to the regional blockade. [5,6] This may prove to be an important clinical consideration for its use as an adjunct to spinal anesthesia. So, this study investigated the properties of propofol when given by intravenous infusion to provide sedation as an adjunct to spinal anesthesia. Keeping this background in the mind this present study was planned to evaluate the hemodynamic stability as a sedative adjunct to spinal anesthesia in parturient undergoing C-Section and compared the requirements for a vasopressor to maintain normotensive.

**MATERIALS AND METHODS:**

**Study area and study population:**

The present study is a randomized prospective study conducted at Medical College & Associated Hospital, Firozabad (UP). After obtaining Institutional Ethics Committee approval and informed patient consent, ASA physical status I-II patients were scheduled for elective cesarean sections.

**Inclusion criteria:**

Healthy parturients aged 18-40 years undergoing elective cesarean sections were included in the study.

**Exclusion criteria:**

Parturients with hypertension, severe fetal distress or those in labor, placental abruption, placenta previa, cord prolapse or less than 30 weeks gestation, twin pregnancy; signs of hypovolemia, oligoanuria, cerebral or visual disturbances.

**Methodology:**

A total of 60 pregnant women aged 18-40 years undergoing a C-Section with spinal anesthesia were randomly allocated into two groups. On arrival in the operating room, standard monitoring was put in place. A spinal anesthetic was performed at L4-5, with the patient in the lateral position. Hyperbaric bupivacaine (Anawin® Spinal 5% Heavy, Neon laboratories) was administered in doses sufficient to provide a satisfactory sensory block for the procedure. Under aseptic precautions, lumbar puncture was done using a 26G Quincke spinal needle at L2-L3/L3-L4 space. Patients in Group P (received a propofol infusion at a rate of 50 µg/kg/min), Inj. Hyperbaric Bupivacaine 0.5%, 2.5 cc (12.5 mg) intrathecally, and Group C (received 100 ml of isotonic solution), Inj. Hyperbaric Bupivacaine 0.5%, 2.5 cc (12.5mg) intrathecally. Thirty-thirty parturients gave propofol (group P), and saline (group C) was allocated to one of two groups according to a randomized sequence. A random selection of study subjects and preparation of drugs was done by a colleague to maintain the blindness of the study.

All of the study subjects in both groups were prepared for surgery in the usual manner. Heart rate, blood pressure, and vitals were monitored. The height of the sensory block was assessed, and after achieving an adequate sensory block (T4 level), the procedure was initiated. The level of sedation was recorded every 5 minutes (Level 4 or 5) on a 5-point sedation score. [Table 1]

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Fully awake and oriented</td>
</tr>
<tr>
<td>II</td>
<td>Drowsy</td>
</tr>
<tr>
<td>III</td>
<td>Eyes closed but arousable to command</td>
</tr>
<tr>
<td>IV</td>
<td>Eyes closed but arousable to mild physical stimulation (earlobe tug)</td>
</tr>
<tr>
<td>V</td>
<td>Eyes closed but unresponsive to mild physical stimulation</td>
</tr>
</tbody>
</table>

The presence of any side effects such as pain or discomfort at the injection site, and respiratory problems. undue hypotension, excitatory phenomena, or movement in response to surgery, was noted. The co-investigators who were blinded to the above groups carried out the necessary assessments. The infusion rate was adjusted during surgery to maintain an appropriate level of sedation;
this was classified as sleep with preservation of eyelash reflex and purposeful reaction to verbal or mild physical stimulation. All patients breathed the air or oxygen-enriched air throughout; no further anesthetic or analgesic drugs were given and the infusion was generally discontinued 5-10 minutes before the end of surgery. All patients were visited 24 hours after their anesthesia, questioned about their satisfaction with the anesthetic technique used, and recalled any specific events during the operation. All side effects during sedation were recorded.

**Statistical analysis:**

All above variables were recorded in a pre-designed, structured schedule during the pre-op assessment, during surgery, and post-op assessment of the study subjects and recorded in MS excel and data analysis using SPSS (Statistical Package for the Social Sciences) for Windows (version 23.0). Categorical variables were described as frequency (percentage), and mean ± standard deviation was used for continuous parameters. In this case, the nonparametric Mann–Whitney test was used for statistical comparisons. Categorical variables were compared between two or more groups using the Chi-square test & unpaired t-test. A two-tailed p-value of <0.05 was considered statistically significant for all analyses.

**RESULTS:**

The demographic distribution of study groups showed that the majority of them were below or up to 30 years of age. The mean age group P was 27.2+/-6.6 years and group C was 30+/-7.3 years. (Table 2)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group P</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Age (years)</td>
<td>27.2+/-6.6</td>
<td>30+/-7.3</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>59.1+/-5.8</td>
<td>58.4+/-4.1</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>153.1+/-7.6</td>
<td>151.4+/-6.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3: Procedural characteristics of the study groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
</tr>
<tr>
<td>Anesthetic time (min)</td>
</tr>
<tr>
<td>Total ephedrine (mg)</td>
</tr>
<tr>
<td>Required ephedrine (u)</td>
</tr>
<tr>
<td>Infusion to surgery (minutes)</td>
</tr>
<tr>
<td>Infusion to the spinal (minutes)</td>
</tr>
<tr>
<td>Awakening time (min)</td>
</tr>
</tbody>
</table>

The average duration of surgery was 60+/-12.7 minutes and the anesthetic time for group P was 68.8+/-2.7 and for group, C was 68.0+/-6.5 and statistically significant (p<0.05). (Table 3) The mean interval between commencing infusion and skin incision was 13.3+/-1.78 minutes in group P. The majority of this time was surgically generated in scrubbing up, gowning, and preparing and draping the patient. In group P, sedation characteristics were good throughout, with no discomfort or pain. Use of Ephedrine in 5 patients of Group P and 15 patients of Group C, respectively (P < 0.05). The requirements for supplemental ephedrine were similar for both groups (Group P, 13.8+/-13 mg, Group C, 12+/-8.5 mg).

The mean time until the patient was fully alert after the operation was 7.8+/-2.4 min (range, 3-17 min) in the patients with propofol-sedation (Group P) but 4.8+/-1.9 min (range, 2-8 min) in those patients under sedation without propofol, Group C (P < 0.05). (Table 3) Recovery was impressively rapid and patients regained full consciousness approximately 4.8+/-1.9 in group P after the end of infusion and were free from minor postoperative sequelae than in group C. All patients expressed their satisfaction regarding the anesthetic technique chosen and didn’t recall any intraoperative events.

**DISCUSSION:**

Propofol by subanesthetic infusion has been shown to provide excellent sedation as an adjunct to the spinal blockade. The technique is safe, simple, and versatile and causes no delay in surgery. Depth of sedation can be easily altered by adjusting the infusion rate and conversion to general anesthesia is simple should the regional block prove ineffective. The technique is relatively free from side effects, in particular the respiratory and cardiovascular depression produced by propofol when given by higher infusion rates for general anesthesia. [7]

In our study, recovery was impressively rapid and patients regained full consciousness at approximately 4.8+/-1.9 in group P after 5 minutes) in propofol sedation. The reduced dose requirement for the elderly is in keeping with previous findings related to propofol for induction of anesthesia. [8]

A dose-related sedative effect has been demonstrated, [9, 10] and non-dose-related amnestic as well. Amnesia is proportional to the administered dose but is incomplete and
less effective than with midazolam.[11] One of the main advantages of propofol is its pharmacokinetic profile, which leads to fast induction, easy alteration of the sedation level, and quick recovery.[12] Hemodynamic impairment, defined as a decrease in arterial pressure and increased incidence of bradycardia is reported at infusion rates of 100–200 mg/h.[13] and is similar if a spinal or axillary block is used.[14] The incidence of nausea and vomiting after propofol infusion is generally low, and an antiemetic effect has been suggested.[15] The provision of good sedation becomes increasingly important if the advantages of the regional techniques are to be exploited to the full. Diazepam, and more recently midazolam, are the most widely used sedative drugs in anesthetic practice.[16] This study has quantified the vasopressor consumption, and standardized vasopressor (ephedrine and phenylephrine) usage in the practice, which could affect the trends of hemodynamic change over time. The limitation of this study was the small sample size and observational study design which was challenging to control all possible co-founders. We could not evaluate all risk factors. We recommend a large-scale population-based study with long-term follow-up.

**CONCLUSION:**
Propofol is the nearest to an ideal agent for sedation during regional anesthesia, because of its favorable pharmacokinetic profile, with rapid onset and rapid, trouble-free recovery. It has concluded that intravenous propofol sedation as an adjunct to spinal anesthesia is associated with a lower incidence of postoperative complications & better compliance. Our findings should be confirmed in future prospective studies. However, more research trials are needed to find optimized doses for different ages, gender, and health status. The development of new modes of administration is a matter of interest and improved quality of sedation is much needed of the hour.

**Acknowledgment:** All the residents of Anesthesia and hospital staff members supported the study.

**Conflict of interest:** None

**REFERENCES:**