CONSCIOUS SEDATION IN DILATATION AND CURETTAGE: COMPARISON OF IV DEXMEDETOMIDINE VERSUS PROPOFOL

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ABSTRACT

Background: Traditionally propofol has been used for providing sedation in dilatation and curettage (D and C). Recently, dexmedetomidine has been tried in a variety of surgeries, but very little evidence exists to support its use.

Aims: The aim was to compare hemodynamic, recovery profile and street fitness of both the drugs along with a degree of comfort experienced by patients.

Materials and Methods: Patients posted for D and C were enrolled in 2 groups (30 each). Both groups received fentanyl 1 μg/kg intravenous (IV) at the beginning of the procedure. Group P received IV propofol in dose of 1 mg/kg over 10 min and Group D received dexmedetomidine at a loading dose of 1 μg/kg over 10 min until Ramsay sedation score reached 3-4. Hemodynamic vitals were compared during and after the procedure. In the recovery room, time to reach modified Aldrete score (MAS) of 8 and patient's and surgeon's satisfaction scores were also recorded and compared.

Results: In Group D, patients had statistically significant lower heart rate at 2, 5, 10 and 15 min as compared to Group P. Hypotension was present more in Group P than Group D (P < 0.05). MAS of 8 was achieved earlier in the dexmedetomidine group (P < 0.05). Group D showed higher patient and surgeon satisfaction scores (P < 0.05).

Conclusion: Dexmedetomidine provide better hemodynamic and recovery profile than propofol. It can be a superior alternative for short surgical day care procedures. The street fitness of the drug which is a major component for day-care anaesthesia was very well taken care of in the study.

KEYWORDS

Conscious sedation, dexmedetomidine, propofol, dilatation and curettage, sedation

INTRODUCTION

Among all the procedure in the day-care domain of gynaecology, dilatation and curettage (D and C) is one of the most common procedures undertaken for infertility. Dysfunctional uterine bleeding, endometrial tuberculosis, endometrial polyp, removal of IUCD and incomplete abortion.

Day care surgery represents high-quality patient care with excellent patient satisfaction. Patients endorse day care surgery with small waiting times, less chances of cancellation, lower rates of infection, and preference of their own surroundings to convalesce.

D and C is done under conscious sedation which is a method of depression of the central nervous system that allows the operator to perform a surgical procedure during which the patient retains protective reflexes. The growing popularity of day-care surgeries has led to the development of newer and efficient drug regimen. As an adjunct to local anaesthesia, this method can be used to take care of perioperative analgesia and anxiety of this day-care procedure.

Different methods to achieve conscious sedation are inhalational anaesthetic agents with oxygen and nitrous oxide, oral or intramuscular medications or intravenous route. Among all of them intravenous route is the most preferred route of achieving adequate analgesia, amnesia, patient’s comfort and the timely completion of the procedure. After a short period of observation of 4 hours with passing off of anaesthetic effect, patient may be discharged.

Due to pharmacological properties and speedy recovery profile, Propofol is a universally used induction agent. Despite its favourable profile, higher doses may be required which can cause adverse cardiorespiratory effects. With addition of adjuvants, requirement of Propofol can be reduced. The α2 adrenoceptor agonists, such as dexmedetomidine, are known to possess amnestic, analgesic, sympatholytic, and antinociceptive properties.

Traditionally Propofol has been providing sedation, amnesia for the procedure with lesser component of analgesia. Before the advent of Dexmedetomidine, Propofol has been a good agent used for sedation. However, it also causes respiratory depression when given along with opioids.

Dexmedetomidine is a new generation highly selective α2-adrenergic receptor (α2-AR) agonist that is associated with sedative and analgesic sparing effects, reduced delirium and agitation, perioperative sympatholysis, cardiovascular stabilizing effects, and preservation of respiratory function.

The Federal Drug administration has approved the use of Dexmedetomidine as a selective analgesic or total anaesthetic in adults undergoing minimally invasive procedures with or without tracheal intubation. It is being increasingly used as a sedative agent for monitored anaesthesia care (MAC) for day-care surgery. Monitored anaesthesia care is specific anaesthesia service for diagnostic and therapeutic procedures performed under local anaesthesia along with sedation and analgesia, titrated to a level that preserves spontaneous breathing and airway reflex. Dexmedetomidine is useful and safe adjunct as it attenuates but does not completely abolish stress-induced sympathoadrenal responses which helps in the comfort of the patient. We undertook this randomized, prospective, double blind study to compare IV Propofol and IV Dexmedetomidine as an agent of conscious sedation in dilatation and curettage.

AIMS AND OBJECTIVES

Primary:
1. To study the hemodynamic changes during the procedure after giving Dexmedetomidine vs Propofol:
   (a). Heart rate (HR) (b). Systolic blood pressure (SBP) (c). Diastolic blood pressure (DBP) (d). Mean arterial pressure (MAP) (e). SpO2 (f). Respiratory Rate
   2. Postoperative sedation
   3. Ramsay sedation score

Secondary:
To study patient’s satisfaction during the procedure
To study post-op PONV and any other complications.

MATERIAL AND METHODS

After obtaining approval from Institutional ethical committee, the prospective, randomized, open labeled, comparative study was undertaken at a tertiary care hospital. After obtaining Informed written consent 60 Adult female patients belonging to ASA Grade 1 and 2 between age 18 to 70 years undergoing elective procedures under sedation were enrolled in the study and were divided into two groups of 30 patients in each group.

Group P (Propofol Group): IV Propofol (1 mg/kg) started 10 minutes before procedure
Group D (Dexmedetomidine Group): IV Dexmedetomidine (1 mg/kg) started 10 minutes before procedure

RESULTS

In Group D, patients had statistically significant lower heart rate at 2, 5, 10 and 15 min as compared to Group P. Hypotension was present more in Group P than Group D (P < 0.05). MAS of 8 was achieved earlier in the dexmedetomidine group (P < 0.05). Group D showed higher patient and surgeon satisfaction scores (P < 0.05).

CONCLUSION:
Dexmedetomidine provide better hemodynamic and recovery profile than propofol. It can be a superior alternative for short surgical day care procedures. The street fitness of the drug which is a major component for day-care anaesthesia was very well taken care of in the study.
in the public, commercial, or not-for-profit sectors

This research did not receive any specific grant from funding agencies

**EXCLUSION CRITERIA:**

1. ASA Grade III and IV
2. BMI>35
3. Patients refusal to participate in the study
4. Renal, hepatic, cardiac, Central Nervous System, respiratory insufficiency
5. Patients allergic to drug, soya bean, egg allergy
6. Patients having history of use of opioid or sedative drug 1 week before surgery
7. Patients on pain perception modifying drug
8. History of arrhythmias

All patients were examined thoroughly and baseline investigations like Hemogram, Urine. and special investigations as per disease condition like - LFT, KFT, RBSL, ECG, Chest X-ray, etc. were done. Pre-operative preparation was done in the form of measuring the base line Pulse rate, Blood pressure, EGG, oxygen saturation. All arrival in operation theatre after confirming patient's starvation status, patient's heart rate, mean arterial blood pressure, oxygen saturation, respiratory rate, ECG, were monitored.

Intravenous (IV) Line was secured with angiocath number 20 gauge and Ringer Lactate solution at 10 ml/kg was started. Oxygen was administered via oxygen mask at 4 L/Shminutes. All patients received premedication with Inj. Ondansetron 0.08mg/kg and Inj. Ranitidine 1 mg/kg IV.

Both groups received fentanyl 1 ug/kg intravenous 5 minutes before the procedure. And was considered as 0 minute.

Group P received IV Propofol in dose of 1.5 mg/kg over 15 minutes.

Group D received Dexmedetomidine as a loading dose of 1 ug/kg over 15 minutes. It was decided not to use dexmedetomidine infusion as the estimated duration of the procedure would not exceed 20-25 minutes in any scenario. So, a loading dose of dexmedetomidine was hypothesized to be sufficient for the procedure.

Systemic arterial blood pressure including systolic, diastolic and mean arterial pressure, heart rate, oxygen saturation, respiratory rate along with Ramsay sedation score were recorded during the procedure and 30 minutes after the procedure.

Heart rate <50 beats/ min or 20% decrease in baseline was to be managed by inj. Atropine 0.6 mg (IV).Mean Arterial blood pressure < 60 mm Hg or 20 % decrease from baseline was to be managed with appropriate fluid therapy, leg elevation. IV Injection Mephenteramine was kept as a rescue drug for hypotension not corrected by above manoeuvre.

Hypoxia: fall in RR to 8 or less breaths per minute or a fall of arterial spo2 <90% were observed, recorded and treated accordingly. If apnoea were to last for more than 15 seconds, it was decided to assist ventilation with Bain's circuit.

Dilatation of the cervix is the most painful part of the procedure. Care was taken that adequate level of sedation was maintained at that time by proper titration of the drugs and the timing of the injection of the drug. In the recovery room, Modified Aldrete Score (MAS) was recorded along with adverse effect such as restlessness, shivering, nausea, vomiting, abdominal discomfort and respiratory depression. On achieving MAS of 8, patients were discharged. The duration of stay in recovery room was recorded. At the end of the procedure, patients and gynaecologist's satisfaction score was recorded. [4=excellent, 3=good, 2=fair, 1=poor]

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors

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**OBSERVATION AND RESULTS**

The data obtained was subjected to statistical analysis using Students unpaired ‘t’ test to find out significant difference between the groups and Chi square test was used for qualitative data. Comparative evaluation was done for age, sex, weight and height. P value was calculated using t test and was statistically insignificant (p>0.05).

**Table 1: Comparison of Mean Pulse Rate patients in Groups:**

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-operative</th>
<th>After 2 minutes</th>
<th>After 5 minutes</th>
<th>After 10 minutes</th>
<th>After 15 minutes</th>
<th>Post operative</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>89.20±4.60</td>
<td>90.90±5.65</td>
<td>95.40±5.34</td>
<td>12.73</td>
<td>P=0.0001(S)</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>80.00±4.60</td>
<td>82.00±5.34</td>
<td>85.00±5.34</td>
<td>14.74</td>
<td>P=0.0001(S)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: Comparison of Mean Systolic Blood Pressure [SBP] of patients in Groups:**

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-operative</th>
<th>After 2 minutes</th>
<th>After 5 minutes</th>
<th>After 10 minutes</th>
<th>After 15 minutes</th>
<th>Post operative</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>126.57±7.97</td>
<td>108.13±4.96</td>
<td>103.13±4.96</td>
<td>11.12</td>
<td>P=0.0001(S)</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>113.67±4.91</td>
<td>91.00±5.34</td>
<td>85.47±3.45</td>
<td>10.63</td>
<td>P=0.0001(S)</td>
<td></td>
</tr>
</tbody>
</table>

The mean SBP preoperatively in group D was 132 mmHg and in group P was 130 mmHg. Later it decreased to 121 mmHg in group D and 101 mmHg in group P at 5 min. The mean SBP postoperatively in group D was 126 mmHg and in group P was 113 mmHg. The p value of all the data after the procedure started was less than 0.001 which constituted that the results were statistically significant.

The fall in systolic blood pressure in the Propofol group is significant than in the Dexmedetomidine group which hints that Group D is haemodynamically more stable.

**Table 3: Comparison of Mean Diastolic Blood Pressure [DBP] of patients in Groups:**

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-operative</th>
<th>After 2 minutes</th>
<th>After 5 minutes</th>
<th>After 10 minutes</th>
<th>After 15 minutes</th>
<th>Post operative</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>70.20±4.60</td>
<td>66.10±4.55</td>
<td>63.40±4.83</td>
<td>12.93</td>
<td>P=0.0001(S)</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>71.90±5.65</td>
<td>69.60±4.78</td>
<td>71.13±4.96</td>
<td>10.12</td>
<td>P=0.0001(S)</td>
<td></td>
</tr>
</tbody>
</table>

The line diagram is depicting and comparing the mean pulse rate of patients included in the study of both the groups.
The mean DBP preoperatively in group D was 87 mmHg and in group P was 85 mmHg. It decreased to 81 mmHg in group D at 2 min. While in group P the fall was observed to 65mmHg at 10 min. The mean DBP postoperatively in group D was 88 mmHg and in group P was 71 mmHg.

The p value after the start of procedure was less than 0.001 which is statistically significant indicating more fall in Propofol group than the dexmedetomidine group.

The time taken to achieve a Ramsay sedation score of 8 was 5.80 minutes in group D and 15.67 minutes in group P with p value being less than 0.001. This shows that Dexmedetomidine group provides better street fitness to the patient which is of utmost essence in the management of daycare surgeries.

**DISCUSSION**

Dilatation and curettage is a minor procedure carried out on a daycare basis in gynaecology. It is done under intravenous sedation mode of anaesthesia. The demographic data that is age, height, weight and the ASA status of the patients was comparable in both the groups paving way for a fair and unbiased comparison between the 2 study groups.

Most of the patients fell in the age group 20 to 55 considering the nature of the study which was dilatation and curettage.

In our study, the mean pulse rate in Dexmedetomidine group reduced from 89 beats per minute [bpm] to 72 bpm postoperatively while in the Propofol group the mean pulse rate remained between the range of 85 to 91 bpm.

Dexmedetomidine is also associated with decrease in heart rate because of its sympatholytic effect which is similar to the other sedatives and a baroreflex effect after vasoconstriction.

According to Wu Y Zhang et al in 2015, there was considerable decrease in heart rate in the Dexmedetomidine group compared to Propofol group administered in the dose of 1ug/kg and 0.6mg/kg respectively. Tomar et al in 2015 showed that there was drop in pulse rate by 18.66% by 5 minutes of giving Dexmedetomidine (P<0.05) Ghali et al in 2011 reported that decrease in heart rate might be attributed to sympatholytic effects and a part of vagal mimetic effects. In our study the systolic blood pressure decreased from 132 mmHg to 126 mmHg postoperatively in the Dexmedetomidine group while it reduced from 110 mmHg to 113 mmHg in the Propofol group. The diastolic blood pressure was 87 mmHg preoperatively in the dexmedetomidine group, it was settled at 88 mmHg while in the Propofol group the preoperative DBP was 85 mm Hg settling at 71 mmHg postoperatively diving upto 63 mmHg at a time of 5 minutes after the start of procedure. This plunge in the diastolic blood pressures make Propofol a relatively hemodynamically unstable drug.

The Mean Arterial Pressure in the dexmedetomidine group remained at a constant range while in the Propofol group, it reduced from 97mmHg to 84 mmHg.

Sethi et al in 2015 concluded that lower values were found in Propofol group causing intense suppression of the pressures than Dexmedetomidine.

The Mean Arterial Pressure in the dexmedetomidine group remained at a constant range while in the Propofol group, it reduced from 97mmHg to 84 mmHg.

The Mean Arterial Pressure in the Dexmedetomidine group was 98% with a fall upto 96 % at 10 minutes of the procedure. A totally different picture was seen in the Propofol group; the preoperative saturation being 99% fell to 93%at 5 minutes,91% at 10 minutes and 95%at 15 minutes of the procedure. The postoperative saturation was 99 % in either group. Togawa et al in 2019 concluded that, although snoring frequently occurred in the dexmedetomidine group, the lowest SpO2 value was found in the Propofol group. Osamu Inatomi et al in 2018 concluded that the frequency of respiratory depression was lower in the Dexmedetomidine group [0%] than the conventional group [6.9%]. Tomar et al in 2015 also concluded that the incidence of desaturation[SpO2<95%] was higher in group P because of tendency of Propofol to cause apnoea and respiratory [hypoxic ventilatory response] depression when given in IV boluses. They also showed that in spontaneously breathing patients, the respiratory depressant effect of Dexmedetomidine was less significant when compared to that of Propofol

The mean SPO2 preoperatively in group D was 98% and in group P was 99%. Subsequently it decreased to 96% in group D at 10 minutes and 91%in group P. It regained to 99% postoperatively in either group.

There was significant fall in the saturation of the Propofol group statistically. This augments the fact that Dexmedetomidine provides better conscious sedation without any respiratory compromise. The mean RR of patients included in the study of both the groups.

The mean preoperative MAP in group D was 99 mmHg and in group P was 97 mmHg. It decreased to 93 mmHg at 5 min in group D and 75 mmHg in group P.

The mean MAP postoperatively in group D was 99 mmHg and in group P was 84 mmHg.

The line diagram depicting and comparing the mean diastolic blood pressure [DBP] of patients included in the study of both the groups.

**Table 4: Comparison of Mean Arterial Pressure [MAP] in Patients:**

<table>
<thead>
<tr>
<th>MAP</th>
<th>Group D</th>
<th>Group P</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative</td>
<td>99.06± 6.18</td>
<td>97.85± 3.81</td>
<td>1.02 P=0.309(NS)</td>
</tr>
<tr>
<td>After 2 minutes</td>
<td>96.17± 7.23</td>
<td>80.53± 5.01</td>
<td>9.85 P&lt;0.0001(S)</td>
</tr>
<tr>
<td>After 5 minutes</td>
<td>93.17± 5.8</td>
<td>75.56± 4.83</td>
<td>12.66 P&lt;0.0001(S)</td>
</tr>
<tr>
<td>After 10 minutes</td>
<td>97.00± 6.18</td>
<td>77.41± 4.96</td>
<td>13.54 P&lt;0.0001(S)</td>
</tr>
<tr>
<td>After 15 minutes</td>
<td>99.07± 6.23</td>
<td>83.16± 4.78</td>
<td>11.09 P&lt;0.0001(S)</td>
</tr>
</tbody>
</table>

The Mean MAP patients in Groups:

The line diagram depicting and comparing the mean arterial pressure of patients included in the study of both the groups.

The mean SPO2, preoperatively in group D was 98% and in group P was 99%. Subsequently it decreased to 96% in group D at 10 minutes and 91% in group P. It regained to 99% postoperatively in either group.

There was significant fall in the saturation of the Propofol group statistically. This augments the fact that Dexmedetomidine provides better conscious sedation without any respiratory compromise. The mean RR preoperatively in group D was 13/minute and in group P was 10/minute. The mean RR postoperatively was 13/minute in either group. The p value was statistically significant during the procedure showing Propofol group causing considerable depression in the respiratory rate of the patients.

One patient in the Dexmedetomidine group showed bradycardia which was treated by injection atropine 0.6 mg IV. One patient in the Propofol group showed hypotension which was managed with aggressive fluid therapy. Otherwise both the groups did not show any other adverse side-effects.

The Ramsay sedation score preoperatively in group D was 4 and group P was 3

30 minutes later it was 2.57 in group D and in group P was 1.13. The p value was below 0.001. The time taken to achieve a Ramsay sedation score in group D was 10.17 minutes while in group P was 7.83 minutes. Thus, patients were better sedated in the postoperative period with group D. The value was less than 0.001.

The patients satisfaction score in group D was 2.93 and in group P was 2.00 with p value being less than 0.001 which showed that results are statistically significant.

Dexmedetomidine group was having better satisfaction scores.

The time to achieve MAS of 8 was 5.80 minutes in group D and 15.67 minutes in group P with p value being less than 0.001. This shows that Dexmedetomidine group provides better street fitness to the patient which is of utmost essence in the management of daycare surgeries.
Ramsay Sedation Score reduced from 4.17 to 2.5 in the Dexmedetomidine group while in the Propofol group it reduced from 3 to 1.13 showing a profound sedation was achieved in the group D. The p value was less than 0.001. Better Ramsay Sedation Score was found in the Dexmedetomidine group and most importantly the time to achieve a dischargeable Modified Aldrete Score was also better in the Dexmedetomidine group giving it an upper hand to Propofol to hit hard and fast but also to wean off which is of utmost importance in the day care surgeries as well.

Anchalee et al in 2012 showed that only regarding the question of the ability to resume normal activities after colonoscopy, there were more patients in the dexmedetomidine group thought that they could resume their normal activities (63.3% in Group P vs. 86.6% in Group D; P=0.018). The recovery period was faster in group D.

The satisfaction scores of both the patient as well as gynaecologist were recorded. They were found better in the dexmedetomidine group compared to Propofol group. Better scores are related to early recovery and minimum side effects experienced. The patient’s satisfaction score in group D was 2.93 while in group P was 2.0. The gynaecologist’s satisfaction score was 3.03 in group D while in group P was 2.07.

One of the main limitations of the study was that being an open labeled Randomized Controlled Trial, there was an inherent risk of bias towards intervention group. All patients were ASA I or II, so the results cannot be generalized to ASA III or IV patients. The sedation was measured by Ramsay Sedation Score. Intraoperative Bispectral Index [BIS] monitoring would have been a better tool to monitor patients. Patients were healthy adults, free of comorbidities that might have seen exaggerated effects of Propofol or dexmedetomidine.

CONCLUSION

After comparison of IV Propofol and IV Dexmedetomidine for giving conscious sedation in 60 patients undergoing dilatation and curettage, it can be concluded that, Injection dexmedetomidine showed reduction in heart rate initially whereas Injection Propofol showed profound reduction in SBP, DBP and MAP saturation and respiratory rate which was significantly different from the dexmedetomidine group which gave appropriate conscious sedation without respiratory depression and adequate Ramsay sedation score. Time to achieve a dischargeable MAS was less in dexmedetomidine group providing a better street-fitness to this group. Patient and gynaecologist’s satisfaction scores were better in the dexmedetomidine group.

Thus, we concluded that better sedation was provided in Dexmedetomidine group but with controlled heart rate and giving an arousable state. It also provided better hemodynamic and recovery profile. It can be safely used as a superior alternative for short surgical daycare procedures.

However further studies in this direction are required to sketch out a role of Dexmedetomidine in providing conscious sedation and use in daycare surgery. The cost of 200 microgram, 2 cc volume injection dexmedetomidine is significantly more than the cost of 200 mg 20 cc injection propofol but not under justified cause, for example, when administering sedation in patients with marginal cardiovascular function. Further study on cost-effectiveness of dexmedetomidine in this kind of operation may be needed.

REFERENCES:

1. DC Dutta textbook of gynaecology 7th edition page no 484.