

A Prospective Randomised Double Blinded Control Study Of Intravenous Dexmedetomidine Versus Propofol For Intraoperative Sedation In Surgeries Under Spinal Anesthesia

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Abstract: Spinal anaesthesia is a popular technic adopted but there are some drawbacks linked with spinal anaesthesia, pain at the puncture site, fear of needles, stress factors in operation room, block level mismatch, monitor sounds and recall of the procedure. The importance of sedation is that it offers analgesia, anxiolysis, and amnesia. Dexmedetomidine and propofol for moderate sedation are best during spinal anaesthesia.

AIM: The objectives are to compare Intraoperative sedation, Intraoperative hemodynamic parameters, Intraoperative respiratory stability and side effects.

METHODOLOGY: Study was approved by institutional medical ethics committee and written informed consent obtained from all patients participating in the study. 150 patients of ASA grade I,II between 18-60 years age of both sexes undergoing various surgeries under spinal anaesthesia. Patients divided into 3 groups containing 50 each according to computer generated random allocation method. Group D received Dexmedetomidine (1mcg/kg loading dose over 10 min followed by maintenance of 0.5 mcg/kg/hr), Group P received Propofol 6mg/kg/hr infused over 10 minutes (1mg/kg bolus) followed by 1.5mg/kg/hr and Group C received normal saline.

RESULTS: Throughout the infusion process, hemodynamic data, respiratory rate, oxygen saturation, sedation, pain, and side effects were recorded. Postoperative hemodynamic measurements, oxygen saturation, sedation, pain scores were obtained:

CONCLUSION: Dexmedetomidine is a safe and attractive drug for sedation in patients undergoing surgeries under spinal anaesthesia

Keywords: Dexmedetomidine, propofol, sedation, general anaesthesia

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I. Introduction

Spinal anaesthesia is popular and offers several benefits to the patient. The top three from the patient's point of view are staying awake, early family contact, and early food intake. For the anaesthetist, cardiovascular and respiratory stability, rapid postoperative recovery, and preservation of protective airway reflexes are the most important advantages of spinal anaesthesia.

Some drawbacks are linked with spinal anaesthesia: pain at the puncture site, fear of needles, stress factors in operation room, block level mismatch, monitor sounds and recall of the procedure. These factors contribute to discomfort, anxiety and restlessness in patients under spinal anaesthesia and stress the importance of sedation that offers analgesia, anxiolysis, and amnesia.

For surgery under spinal anaesthesia, sedation is a valuable tool to make it more convenient for the patient, the anaesthetist, and the surgeon.

The elderly population, because of the increased risk of haemodynamic complications need more careful titration for sedation.

Sedation is a drug-induced depression of consciousness, a continuum culminating in general anaesthesia. The ASA defines three levels of sedation

Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Cognitive function and physical coordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate sedation describes a state where a purposeful response to verbal commands either alone (approximating conscious sedation) or accompanied by light tactile stimulation is maintained. Conscious sedation is defined as 'a technique in which the use of a drug or drugs produces a state of depression of the

central nervous system enabling treatment to be carried out, but during which *verbal contact with the patient is maintained* throughout the period of sedation. The drugs and techniques used should carry a *margin of safety* wide enough to render loss of consciousness unlikely⁷. The endpoint is clearly defined and wide margins of safety stipulated. The airway is normally unaffected and spontaneous ventilation adequate.

Deep sedation describes a state where the patient cannot easily be aroused but responds purposefully to repeated or painful stimulation. It may be accompanied by clinically significant ventilatory depression. The patient may require assistance maintaining a patent airway and positive pressure ventilation.

Passing along the sedation continuum from minimal through moderate to deep sedation, and ultimately to general anaesthesia, we see increasing depression of other physiological systems. The likelihood of adverse events increases, which if not managed promptly, and effectively, may progress to poor outcomes. The increasing depth of sedation needs more care to ensure safe sedation practice.

Aiming for *Conscious Sedation* as the target state, through careful titration to effect, airway interventions are not required, ventilation is normally adequate, and cardiovascular function is maintained. This is the rationale behind defining conscious sedation as a 'safe' target state.

Clinical and instrumental monitoring to a degree relevant to the patient's medical status and the sedation method should be used. Pulse oximetry, ECG, and automated non-invasive arterial pressure monitoring needed. Regular communication with the patient in addition to putting them at ease allows monitoring of the level of sedation. If verbal communication is lost, the patient requires the same level of care as for general anaesthesia. Monitoring should be continued through recovery until the discharge criteria are met.

Respiratory depression may accompany the use of i.v. sedatives. Oxygen, via nasal cannulae, should be administered from the commencement of sedation, through to readiness for discharge from recovery, particularly for patients with relevant medical conditions, where multiple drug techniques or anaesthetic drugs are used, or deeper levels of sedation administered. While administration of oxygen prevents hypoxia, it may mask hypoventilation

Continuum of depth of sedation: definition of general anaesthesia and levels of sedation/analgesia.

	Minimal sedation/anoxiolysis	Moderate sedation/analgesia ('Conscious sedation')	Deep sedation/analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained

II. Aims And Objectives

This is a prospective Randomised double blinded study to compare efficacy of intravenous Dexmedetomidine and propofol for moderate sedation during spinal anaesthesia. Our aims and objectives are to compare

- 1) Intraoperative sedation
- 2) Intraoperative hemodynamic stability
- 3) Intraoperative respiratory stability
- 4) Side effects

The ideal sedative agent should also have minimal side-effects, particularly a lack of haemodynamic impairment, respiratory depression, and thermoregulatory interference which may already be caused by a spinal block.

III. Dexmedetomidine

Dexmedetomidine is a selective α_2 -receptor agonist, with an α_2/α_1 binding affinity ratio of 1620:1; with eight times more affinity to α_2 receptors than clonidine. This drug has a favorable pharmacologic profile owing to its sympatholytic, sedative, analgesic (opioid-sparing), and anxiolytic, and anesthetic drug-sparing effects and, of note, without respiratory depression ..

Drug administration

The dexmedetomidine infusion is begun at an infusion rate of $0.7 \mu\text{g kg}^{-1} \text{h}^{-1}$ and is then adjusted according to response within the dose range $0.2\text{--}1.4 \mu\text{g kg}^{-1} \text{h}^{-1}$. In contrast to its use in anaesthesia, it is recommended that no loading dose is given when used for sedation in the ICU. There is no published experience with infusions lasting >14 days.

The recommended dosing regimens when using dexmedetomidine for procedural sedation in the USA are described below.

A loading infusion of 1 µg kg⁻¹ over 10 min

A reduced loading infusion of 0.5 µg kg⁻¹ over 10 min is recommended for patients over 65 years of age and when less invasive procedures are to be undertaken (e.g. ophthalmic).

A maintenance infusion

This is generally initiated at 0.6 µg kg⁻¹ h⁻¹ and titrated to the desired clinical effect between doses of 0.2 and 1.0 µg kg⁻¹ h⁻¹. Maintenance infusion at 0.7 µg kg⁻¹ h⁻¹ is advised when performing awake fiberoptic intubation until the tracheal tube is secured..

PROPOFOL

Propofol is the most frequently used IV anesthetic today . Insoluble in water, propofol was first formulated with Cremophor EL , but several anaphylactoid reactions were described successively so that it was then prepared as an oil in water emulsion. The formulation that followed the removal of Cremophor consists of 1% propofol in water, 10% soybean oil, 2.25% glycerol, and 1.2% purified egg phosphatide; it provides 1.1kcal/ml from fat and should be counted as a caloric source. Reports of infections in patients receiving propofol prompted the addition of 0.005% ethylenediaminetetraacetic acid (EDTA) to retard bacterial growth . This formulation has a pH of 7 and the appearance of a slightly viscous, milky white substance. Mechanism of action:-

Propofol acts as a hypnotic agent by enhancing γ -aminobutyric acid (GABA)-induced chloride current coming after its binding to the β -subunit of GABA receptor . Propofol, through its action on GABA receptors in the hippocampus, inhibits acetylcholine release in the hippocampus and prefrontal cortex, but it seems to also play a role in the case of the α 2-adrenoreceptor system and in inhibition of the NMDA subtype of glutamate receptor

Indicated for induction and maintenance of anesthesia and sedation in and outside the operating room and ICU. It has anxiolytic/sedative/hypnotic, antiemetic, antipruritic, anticonvulsant, bronchodilatory, muscle relaxant, and possibly anti-inflammatory and antiplatelet effects .

IV. Methodology

STUDY PERIOD :- Between December 2016 and August 2018

STUDY DESIGN:- Prospective randomised double blinded study

APPROVAL:-Study was approved by institutional medical ethics committee and written informed consent obtained from all patients participating in the study.

STUDY POPULATION:- 150 patients of ASA I ,II between 18-60 years age of both sexes undergoing various surgeries under spinal anesthesia.

STUDY GROUPS:-Patients divided into 3 groups containing 50 each according to computer generated random allocation method.

Group D recieved Dexmedetomidine.(1mic/kg loading dose over 10 min followed by maintenance of 0.5 mic/kg/hr)

Group P recieved Propofol 6mg/kg/hr infused over 10 minutes (1mg/kg bolus)followed by 1.5mg/kg/hr

Group C recieved normal saline

PATIENT SELECTION:-

INCLUSION CRITERIA:-

- 1) Elective surgeries
- 2) Age group 18-60 yrs
- 3) ASA grade I & II
- 4) Patients of both sexes

EXCLUSION CRITERIA

- 1) H/O Renal and hepatic disorders
- 2) H/O concomitant use of alpha2 antagonists,calcium channel blockers,beta blockers,ACE inhibitors
- 3) Dysrhythmias
- 4) ASA 3 & 4
- 5) Morbid obesity
- 6) Pregnant & lactating women
- 7) Patients with known asthma & COPD
- 8) Coagulopathy
- 9) MI in last 6 months
- 10) Allergy to study drugs

Pre anaesthetic evaluation done on day before surgery and necessary investigations advised.(complete hemogram, TLC, Differential count, Bleeding time, clotting time, Random blood sugar, Blood urea,Serum creatinine,Chest Xray for age > 35 yrs,ECG,HIV,HBSAg)Patients were explained in detail about the spinal anaesthesia,surgery and sedation.

Patients meeting inclusion criteria were taken into study after taking informed consent and kept nil by mouth overnight. No premedication given to any patient.

On day of surgery patients were taken into operating room. preoperative sedation level assessed using Ramsay sedation score. Patients connected to standard multipara monitors for Noninvasive blood pressure, pulse oximeter and electrocardiogram. Baseline measurements taken for bp,hr,rr,spo2 A large vein chosen for intravenous access and 18G cannula secured All patients preloaded with 15ml/kg of ringer lactate prior to spinal anaesthesia . Under aseptic conditions lumbar puncture done at L3-4 interspace with Quincke 25 G spinal needle and 3.5 ml 0.5% hyperbaric bupivacaine given after free flow of csf.Patients were made to lie in supine position Study drugs started according to group allocated after assessment of maximum sensory blockade The onset of sedation was taken as time to reach RSS Score of 3 as it closely meets condition of moderate sedation Level of sedation assessed every 5 min interval and infusion stoped 10 min before completion of surgery ECG,Mean Blood pressure,Respiratory rate,Spo2,Etco2 recorded every 5 min intervals after baseline measurements till end of procedure Recovery time (time taken to return to sedation score to baseline after stopping infusion of study drugs) recorded in all patients Side effects nausea, vomiting, hypotension, respiratory depression ,shivering noted During surgery if R,recordedesp rate < 10/min or Spo2 < 92% were recorded,4L/min of supplemental oxygen was given with nasal cannula and infusion rate of drug reduced Hypotension (MAP< 50mmHg) was treated with fast 0.9% normal saline and I.v bolus of mephenteramine 3mg and infusion rate of drug reduced Bradycardia (HR<50) treated with I.v atropine 0.5 mg and infusion rate of drug reduced.

Statistical Analysis: For continuous variables,the summary statistics of ,mean ,Standard deviation SD were used. Age and weight means of 3 groups were analyse,mean ,Standard d by ANOVA test. Gender was analysed by chisquare test. If p value less than 0.05 the results are considered statistically significant. Data was analyzed by using spss version 16 .

V. Results

Table1: Distribution of study participants based on demographic data

Variable	Group D (Dexmedetomidine) Mean±S.D	Group P (Propofol) Mean±S.D	Group C (Control) Mean±S.D	p value
AGE	37.96±11.89	35.78±12.32	37.78±11.51	0.598
WEIGHT	61.88±7.90	57.62±7.94	61.88±7.904	0.009
DURATION OF SURGERY	85.60±11.36	86.60±14.92	85.60±11.36	0.901
GENDER (M:F)	27:23	27:23	28:22	0.97

.No significant difference between groups in age,weight ,duration of surgery and gender and all three groups comparable as p value>0.05

No significant difference between groups in age as p value is 0.785(>0.05)

No significant difference between groups in distribution of patients in ASA grade I and II as p value is 0.958(>0.05)

INTRAOPERATIVE SPO2 BETWEEN STUDY GROUPS

Parameter	Group D	Group P	Group C
Baseline	99.48+ 0.50	99.00+0.51	99.48+ 0.50
5 min	99.27+0.57	99.13+0.49	99.27+0.57
10 min	99.44+0.50	99.31+0.69	99.44+0.50
15 min	99.13+0.70	99.00+0.51	99.13+0.70
30 min	99.35+0.48	99.00+0.98	99.35+0.48
45 min	98.96+0.58	98.88+0.53	98.96+0.58
60 min	98.92+0.50	98.96+0.46	98.92+0.50
75	99.00+0.36	98.94+0.53	99.00+0.36
90	99.00+0.00	99.06+0.36	99.00+0.00
105	99.00+0.36	98.92+0.28	99.00+0.36
120	99.00+0.24	99.00+0.24	99.00+0.24

P value for intraoperative spo2 for 3 groups is 0.205 >0.05 and difference between study groups is not statistically significant

Table: Comparison of MAP between three groups

MAP	Group	N	Mean	Standard deviation	P value
MAP basal	GROUP D	50	78.000	4.7164	0.78
	GROUP P	50	78.320	4.8548	
	GROUP C	50	77.660	4.7579	
MAP 5min	GROUP D	50	76.540	4.6256	0.001
	GROUP P	50	67.380	5.3026	
	GROUP C	50	74.840	3.4662	
MAP 10min	GROUP D	50	77.120	5.3781	0.001
	GROUP P	50	67.360	5.6668	
	GROUP C	50	77.420	3.8866	
MAP 15min	GROUP D	50	69.980	6.3711	0.001
	GROUP P	50	64.660	3.8998	
	GROUP C	50	77.360	3.9732	
MAP 30min	GROUP D	50	77.040	3.7578	0.001
	GROUP P	50	63.620	3.1873	
	GROUP C	50	76.060	2.9236	
MAP 45min	GROUP D	50	76.560	4.1313	0.001
	GROUP P	50	66.840	5.1680	
	GROUP C	50	76.560	4.1313	
MAP 60min	GROUP D	50	76.080	4.2419	0.001
	GROUP P	50	64.820	4.1191	
	GROUP C	50	76.080	4.2419	
MAP 75min	GROUP D	50	73.780	4.7307	0.001
	GROUP P	50	67.120	3.3965	
	GROUP C	50	73.780	4.7307	

Baseline MAP was 78.00+/- 0.78 in 78.32+/- 4.85 Group D in Group P & 77.66+/-4.75 in Group C. Mean arterial pressure at baseline was comparable among groups. MAP decreased significantly from 5 minutes with p value < 0.05

MAP was significantly lower in Group P compared to other groups with p value less than 0.05.

MAP of Group P at 5 min is 67.380+/- 5.3026 and is lower than control group 74.840+/- 3.4662 and is statistically significant p value 0.001 (>0.05)

TABLE: POST OPERATIVE MAP COMPARISON

MAP	GROUP	N	MEAN	S.D	P VALUE
MAP 5min	Group D	50	86.960	6.3018	0.001
	Group P	50	78.520	6.0042	
	Group C	50	79.060	6.2740	
MAP 15min	Group D	50	88.960	3.7196	0.001
	Group P	50	80.680	5.8255	
	Group C	50	80.820	6.0666	
MAP 30min	Group D	50	89.380	3.7082	0.001
	Group P	50	80.640	5.7170	
	Group C	50	80.820	5.7948	
MAP 60min	Group D	50	89.520	4.0569	0.001
	Group P	50	80.880	5.7628	
	Group C	50	80.960	5.7781	

Table : Comparison of RR between three groups

Respiratory rate	Group	N	Mean	Standard deviation	P value
RR 5min	GROUP D	50	13.560	1.3577	0.24
	GROUP P	50	14.020	1.9639	
	GROUP C	50	13.560	1.3577	
RR 10min	GROUP D	50	13.480	1.3886	0.84
	GROUP P	50	13.620	1.3834	
	GROUP C	50	13.480	1.3886	
RR 15min	GROUP D	50	13.420	1.3864	0.34
	GROUP P	50	13.760	1.2707	
	GROUP C	50	13.420	1.3864	
RR 30min	GROUP D	50	13.360	1.4251	0.67
	GROUP P	50	13.600	1.8295	
	GROUP C	50	13.360	1.4251	
RR 45min	GROUP D	50	13.360	1.4251	0.86
	GROUP P	50	13.500	1.6444	
	GROUP C	50	13.360	1.4251	
RR 60min	GROUP D	50	13.480	1.3886	0.96
	GROUP P	50	13.540	1.2324	

	GROUP C	50	13.480	1.3886	
RR 75min	GROUP D	50	12.980	1.6841	0.33
	GROUP P	50	13.360	.9205	
	GROUP C	50	12.980	1.6841	

No statistical difference in respiratory rate among groups as p value $p > 0.05$

Table: HEART RATE COMPARISION AMONG THREE GROUPS

Heart rate	Grouping	MEAN	S.D	P VALUE
HR basal	group D	76.200	6.4428	0.04
	GROUP P	80.667	9.5638	
	GROUP C	76.286	6.4807	
HR5min	group D	75.200	5.6605	0.001
	GROUP P	80.961	9.8832	
	GROUP C	77.327	2.8460	
HR10min	group D	70.700	5.6829	0.001
	GROUP P	82.020	9.4456	
	GROUP C	76.490	5.0296	
HR15min	group D	67.040	5.5253	0.001
	GROUP P	80.882	9.8644	
	GROUP C	77.286	6.9011	
HR30min	group D	65.840	4.8418	0.001
	GROUP P	79.510	9.4707	
	GROUP C	76.265	7.7883	
HR45min	group D	66.500	5.0153	0.001
	GROUP P	79.824	10.5806	
	GROUP C	78.714	6.6521	
HR60min	group D	65.560	4.4865	0.001
	GROUP P	78.314	10.0965	
	GROUP C	78.286	9.5175	
HR75min	group D	65.000	3.8809	0.001
	GROUP P	77.922	10.6430	
	GROUP C	76.551	5.4851	

Heart rate was lower in Group D from 5 min when compared with other groups with p value less than 0.05

TABLE: POST OPERATIVE HEART RATE COMPARISION

HEART RATE	GROUP	N	MEAN	S.D	P VALUE
HR5min	Group D	50	66.400	4.4630	0.001
	Group P	50	77.860	8.4056	
	Group C	50	67.840	5.2152	
HR15min	Group D	50	69.160	4.1814	0.001
	Group P	50	78.260	7.5182	
	Group C	50	69.600	5.0143	
HR30min	Group D	50	69.200	4.0608	0.001
	Group P	50	78.480	7.0167	
	Group C	50	69.400	4.6114	
HR60min	Group D	50	69.240	3.9152	0.001
	Group P	50	78.440	7.7121	
	Group C	50	69.320	3.9715	

Heart rate was significantly lower in post operative period in Group D compared to other groups

Table : RSS COMPARISION AMONG THREE GROUPS

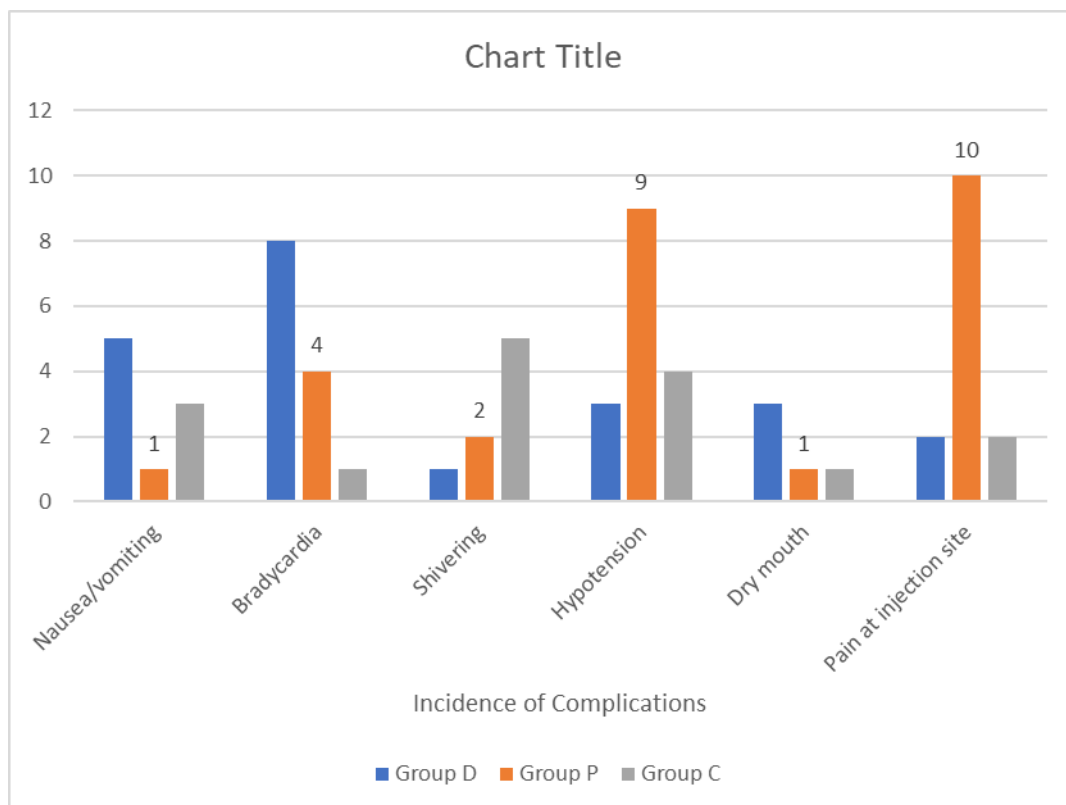
RSS	Grouping	MEAN	S.D	P VALUE
RSS5min	group D	1.400	.4949	0.03
	GROUP P	1.431	.5002	
	GROUP C	1.204	.4072	
RSS10min	group D	2.720	.5360	0.001
	GROUP P	2.824	.3850	
	GROUP C	1.531	.5042	
RSS15min	group D	3.000	.2857	0.001
	GROUP P	2.824	.3850	
	GROUP C	1.531	.5042	
RSS30min	group D	3.060	.2399	0.001
	GROUP P	2.824	.3850	
	GROUP C	1.408	.4966	
RSS45min	group D	3.000	.0000	0.001
	GROUP P	2.902	.3608	

	GROUP C	1.592	.4966	
RSS60min	group D	3.000	.0000	0.001
	GROUP P	2.941	.2376	
	GROUP C	1.796	.4072	
RSS75min	group D	2.960	.1979	0.001
	GROUP P	2.882	.3254	
	GROUP C	1.735	.4461	

TABLE: RSS COMPARISION POSTOPERATIVE

RSS	GROUP	N	MEAN	S.D	P VALUE
RSS 5mni	Group D	50	1.980	.6848	0.001
	Group P	50	2.280	.4536	
	Group C	50	1.760	.4764	
RSS 15min	Group D	50	1.060	.2399	0.001
	Group P	50	1.860	.4522	
	Group C	50	1.060	.2399	
RSS 30min	Group D	50	1.000	.0000	0.001
	Group P	50	1.640	.5253	
	Group C	50	1.000	.0000	
RSS 60min	Group D	50	1.020	.1414	0.001
	Group P	50	1.480	.5047	
	Group C	50	1.020	.1414	

RSS on arrival was 1.98 +/- 0.68 in Group D ,2.28 +/- 0.45 in Group P and 1.76+/-0.47 in Group C
Distribution of study participants based on side effects



Incidence of Shivering was less in Group D compared to other groups
 Incidence of Bradycardia higher in Group D compared to other groups
 Incidence of hypotension is more in Propofol compared to other groups
 There are no neurological complications and desaturation episodes in any cases

VI. Discussion

Spinal anaesthesia is popular and offers several benefits to the patient. The top three from the patient's point of view are staying awake, early family contact, and early food intake. For the anaesthetist, cardiovascular and respiratory stability, rapid postoperative recovery, and preservation of protective airway reflexes are the most important advantages of spinal anaesthesia.

Some drawbacks are linked with spinal anaesthesia: pain at the puncture site, fear of needles, stress factors in operation room, sounds of monitors, block level mismatch, and recall of the procedure. These factors contribute to discomfort, anxiety and restlessness in patients under spinal anaesthesia and stress the importance of sedation that offers analgesia, anxiolysis, and amnesia.

For surgery under spinal anaesthesia, sedation is a valuable tool to make it more convenient for the patient, the anaesthetist, and the surgeon.

Sedation is a drug-induced depression of consciousness, a continuum culminating in general anaesthesia

Passing along the sedation continuum from minimal through moderate to deep sedation, and ultimately to general anaesthesia, we see increasing depression of other physiological systems. The likelihood of adverse events increases, which if not managed promptly, and effectively, may progress to poor outcomes. The increasing depth of sedation is therefore accompanied by an escalation in the level of competency required to ensure safe sedation practice.

Aiming for *Conscious Sedation* as the target state, through careful titration to effect, airway interventions are not required, ventilation is normally adequate, and cardiovascular function is maintained. This is the rationale behind defining conscious sedation as a 'safe' target state.

Clinical and instrumental monitoring to a degree relevant to the patient's medical status and the sedation method should be used. Pulse oximetry, ECG, and automated non-invasive arterial pressure monitoring needed. Regular communication with the patient in addition to putting them at ease allows monitoring of the level of sedation. If verbal communication is lost, the patient requires the same level of care as for general anaesthesia. Monitoring should be continued through recovery until the discharge criteria are met.

Laosuan S, Pongruetdee S, Thaharavanich R¹. Comparison of effective-site target controlled infusion and manually controlled infusion of propofol for sedation during spinal anaesthesia. *J Med Assoc Thai.* 2011 Aug;94(8):965-

They concluded that the clinical benefit when used for sedation during spinal anaesthesia of MCI was not different from TCI. There were complications in the TCI group more than the MCI group. In our study propofol was given by intravenous infusion titrated to desired sedation levels and careful monitoring of all vitals intraoperatively every 5 minutes and all patients even followed up for vitals and sedation assessment in post operative ward for at least 1 hr

Arain SR, Ebert TJ², conducted a randomised double blinded clinical study to find the efficacy, side effects, and recovery characteristics of dexmedetomidine versus propofol when used for intraoperative sedation. They concluded that Dexmedetomidine may be useful for perioperative sedation. It has a slower onset and offset of sedation compared with propofol. In our study also, Dexmedetomidine group has slower onset and offset of sedation compared to Propofol group

Kiwi Mantan, Anita Pareek, Rashmi Jain, Anju Meena, Pramila Soni, and Aditi Sharma³ did a study for COMPARATIVE EVALUATION OF DEXMEDETOMIDINE, PROPOFOL AND MIDAZOLAM FOR INTRAOPERATIVE SEDATION IN REGIONAL They concluded that onset of sedation was earlier in patient who received IV propofol infusion under spinal anaesthesia as compared to patients who receive IV infusion of midazolam or dexmedetomidine or normal saline. In our study also the onset of sedation was earlier with propofol group compared to other groups.

Pratibha Jain Shah, Kamta Prasad Dubey, Kamal Kishore Sahare, and Amit Agrawal⁴ conducted a comparative study with Intravenous dexmedetomidine versus propofol for intraoperative moderate sedation during spinal anaesthesia They concluded that Dexmedetomidine with its stable cardio-respiratory profile, better sedation, could be a valuable adjunct for intraoperative sedation during spinal anaesthesia. These findings are similar to the clinical outcomes in our study

The present study is to compare efficacy of intravenous dexmedetomidine with intravenous propofol compared with a control on adults of 18-60 yrs of age undergoing surgeries under spinal anaesthesia. Inj dexmedetomidine and propofol doses are reported to be safe and effective as in studies done by **Kshitija Bhagavan Savant et al, Abdelkarim S. AIOweidi et al, Arain SR et al, Al-Mustafa MM et al, Kumar Singh R et al⁵**

In our study the baseline mean arterial pressure, heart rate, respiratory rate, Ramsay sedation score are not statistically significant as p value is > 0.05 .

Mean arterial pressure was significantly lower in Group P from 5 minutes compared to other groups and persisted throughout surgery. But the incidence of hypotension as a side effect is less as vasodilatory and myocardial depressant effects are concentration dependant and given that concentrations achieved with induction doses are higher than those from continuous infusion.

Mean arterial pressure of Group D is lower than control group from 15 minutes but maintained higher values than Group P. This could be due to the property of dexmedetomidine causing decrease sympathetic outflow and decreased catecholamines would cause decrease in MAP. However larger doses of dexmedetomidine will have a direct effect on post synaptic vascular smooth muscle to cause vasoconstriction and the sympatholytic effects are opposed by direct α_2 mediated vasoconstriction. These results correlate with the studies of Arian, et al; Al Mustafa, et al.; Mahmoud, et al.⁶

No statistically significant differences in Respiratory rate and spO_2 are observed among three groups as dexmedetomidine and propofol have minimal respiratory depression when used as sedative agents

Heart rate was statistically lower in Group D from 5 minutes compared to other groups and persisted throughout surgery. This could be due to sympatholytic properties and vagal mimetic effects of Dexmedetomidine. These results are similar to that of Mustafa, et al. And Mahmoud, et al.

Ramsay sedation scores in Group P showed significant difference from Group D from 15 minutes with persistently deeper sedation score (till the end of surgery) in Group D. The early onset of sedation in propofol group compared to Group D is because propofol is highly lipophilic and distributes rapidly into CNS. These results correlate with that of Abdelkareim, et al.⁷

Both Group D and Group P have a deeper sedation level than control group. This finding is supported by results of Arian et al, Kaya et al and Hoy and Keating

Incidence of Shivering was less in Group D compared to other groups

Incidence of Bradycardia higher in Group D compared to other groups

Incidence of hypotension is more in Propofol compared to other groups

There are no neurological complications and desaturation episodes in any cases

VII. Conclusion

From our study, we conclude that Dexmedetomidine in comparison to propofol causes:-

1. Better sedation
2. Better hemodynamic stability
3. Less significant side effects

Dexmedetomidine helps in attaining sedation without any ventilatory depression. It does not cause significant hypotension and has lesser significant side effects

Hence, we conclude that, Dexmedetomidine is a safe and attractive drug for sedation in patients undergoing surgeries under spinal anaesthesia

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