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Original Article

Comparison between Effects of Ketofol and Dexmedetomidine as Sedative in Elective Caesarean Section under Subarachnoid Anaesthesia

*Md Enayet Karim[1], RAM Mostafijur Rashid[2], Mohammad Saleh Akram[3], Reza Ershad[4]

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Abstract:

Background: *Regional anaesthesia has become an important anaesthetic technique now a days. The use of spinal (subarachnoid) anaesthesia is often limited by the unwillingness of patients to remain awake during surgery. Pharmacologically induced tranquility improves acceptance of regional technique.*

Objective: *This study compares Ketofol (Ketamine + Propofol) and Dexmedetomidine in terms of onset and recovery of sedation, haemodynamic effects, respiratory effects and adverse effects of both the drugs during elective Caesarian section under spinal anaesthesia.*

Materials and Methods: *This randomized clinical trial included 60 ASA (American Society of Anaesthesiologists) grade I and II patients between age 20-40 years undergoing elective Caesarean sections under Subarachnoid anaesthesia during the period January 2022 to June 2022. Patients were randomly allocatedto one of two groups: Ketofol group (Group KP, n=30), who received Ketofol in a single dose of 0.5mg/kg (Ketamine-0.5mg/ kg+Propofol -0.5mg/kg) and Dexmedetomidine group (Group D, n=30), who received Dexmedetomidine in a single dose of 2mcg/kg. Spinal anaesthesiawas conducted by injecting a hyperbaric solution of 0.5% bupivacaine 3ml through a 25G spinal needle at L3-4 level. All parameters were documented at 5 min intervals until arousal of the patient. The onset of sedation i.e. time from iv (intravenous) injection of Ketofol or Dexmedetomidine to closure of eye lids (OAA/S score of 3) and the arousal time from sedation i.e. time from closing of the eye lids to OAA/S score of 5 (patient is awake clinically) were noted. Any complication during operation was documented. Patient's satisfaction with the sedation was assessed by the 5 point 'Likert verbal rating scale'.*

Results: *There was no significant difference of mean blood pressure and mean heart rate between the two groups in different time intervals (P>0.05). Time of onset of sedation was significantly delayed in Dexmedetomidine group (P<0.001). The arousal time i.e. duration of sedation was comparable between the two groups (P>0.05). Ketofol was associated with significantly higher incidence of some adverse effects like pain in arm during drug administration than Dexmedetomidine (33.33% vs 10%, P<0.05). Satisfaction with sedation was comparable between the two groups (66.66% vs 86.66%, P value 0.136).*

Conclusion: *As duration of sedation was comparable between the two drugs but adverse effects was less with Dexmedetomidine, it is recommended that Dexmedetomidine is a better choice than Ketofol for sedation in single dose technique during Subarachnoid block for Caesarean section.*

Keywords: *Ketofol,Dexmedetomidine, Sedation, Subarachnoid anaesthesia.*

Introduction

Spinal (Subarachnoid) anaesthesia is the method of choice for elective Caesarean section. It allows mother to be involved in the child's delivery but also exposes them to awareness related stress during the procedure. The stress intensity is higher in women undergoing a Caesarean section compared with women delivering spontaneously.[1] The use of pharmacological sedation after extraction of the fetus by Caesarean section under Subarachnoid anaesthesia is useful in some patients e.g. those presenting with high stress. Enhanced stress can result from poor fetal health after delivery, discomfort associated with immobilization on the operating table, chills that accompany anasthesia, nausea, vomiting and environment of operating room.[2]

Sedation is a valuable tool to provide general comfort for the patient. Oversedation may jeopardize the safety of the patient. While levels of sedation progress in a dose response continuum, it is not always possible to predict precisely how an individual patient will respond to a particular dose.[3] Oversedation may be associated with untoward effect of respiratory and cardiovascular depression resulting in higher chances of airway instrumentation and hypotension leading to a prolonged stay in the post anaesthetic care unit, entailing increased burden on staff, bed availability and associated costs.[4,5] Thus judicious use of sedation can make surgeries under spinal anaesthesia more comfortable for the patient, the surgeon and the anaesthesiologist. As a result, it can increase the patient's acceptance of regional anaesthetic technique.[6]

Ketofol, a combination of the drugs ketamine and propofol has good analgesic and sedative properties in addition to fast onset of action. Sedation with Ketofol decreases the side effects of both ketamine and propofol as they potentiate each other and thus smaller doses are used.[7]Dexmedetomidine is a highly selective α2 agonist that has sedative, analgesic,

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anxiolytic and amnesic effects without a significant respiratory depression. It displays a dose dependent blood pressure response. It has a sympatholytic effect through decreasing the concentration of norepinephrine which in turn decreases the heart rate and blood pressure.[8]

There are a good number of studies regarding the use of sedative agents during regional anaesthesia but it is scarce in case of Caesarian section where a pregnant woman has anatomical and physiological changes from a non-pregnant woman.The aim of this study was to compare the time of onset and recovery from sedation with Ketofol and Dexmedetomidine, to evaluate and compare the properties of both drugs in terms of haemodynamic effects, respiratory effects and adverse effects, as adjuncts to spinal anaesthesia.

Methods and Materials

This randomized clinical trial included 60 ASA (American Society of Anesthesiologists) grade I or II patients between age 20-40 years undergoing elective Caesarean sections under Subarachnoid anaesthesia during the period January 2022 to June 2022 in Combined Military Hospital, Chattogram. The exclusion criteria were positive history of drug allergies, patients suffering from heart disease, hypertension, diabetes, spinal deformity, neurological disorder, any bleeding disorder and unwilling to accept sedation during spinal anaesthesia. Patients were randomly allocated to one of two groups: Ketofol group (GroupKP, n=30), who received Ketofol in a single dose of 0.5mg/kg (propofol 0.5mg/kg and ketamine 0.5mg/kg) and Dexmedetomidine group (Group D, n=30), who received Dexmedetomidine in a single dose of 2mcg/kg (over 10min). Ketofol was prepared with Ketamine: Propofol mixture in 1:1 ratio in a 10 ml syringe which contained Ketamine 5mg/ml and Propofol 5mg/ml. Written informed consent were taken from all participants. Ethical approval was obtained from proper authority. They were fasted for a minimum of 6 hours before surgery. No preoperative opioid or prophylactic antiemetic were given. No other preoperative medication was allowed. All patients were monitored with electrocardiograph, non-invasive blood pressure and pulse oximeter monitor. Baseline vital parameters were recorded.

Preloading was done with 300ml Ringer lactate within 5-10 minutes prior to block. Spinal anaesthesia was conducted by injecting a hyperbaric solution of 0.5% bupivacaine 3ml through a 25G spinal needle at L3-4 level. After spinal block, patients were placed on the operating table in horizontal position. Sedation with Ketofol and Dexmedetomidine was administered after extraction of the foetus. O_2 inhalation by ventimask was given when SpO_2 (saturation percentage of arterial oxygen) came down below 90% and vasopressor was given if MAP (mean arterial pressure) decreased beyond 20% of baseline. MAP was measured continually at 5 min interval and heart rate (HR), SpO_2 were monitored throughout the surgery. All parameters were documented at 5 min intervals until arousal of the patient. The onset of sedation i.e. time from iv injection of Ketofol or Dexmedetomidine to closure of eye lids (OAA/S score of 3) and the arousal time from sedation i.e. time from closing of the eye lids to OAA/S (Observer's Assessment of Alertness/ Sedation) score of 5 (patient is awake clinically) were noted. Any complication during operation was documented. The patient's satisfaction with the sedation was assessed by the 5 point 'Likert verbal rating scale' with some questions like 'where will you put your experience with this sedation on the scale?' in a language which the patient understands, at a point of time when the patient had a mental state suitable for communication.

Observer's Assessment of Alertness/ Sedation (OAA/S) Scale:

Category	Observation	Score Level
Responsiveness	Responds readily to name spoken in normal tone	5
	Lethargic response to name spoken in normal tone	4
	Responds only after name is called loudly and/or repeatedly	3
	Responds only after mild prodding or shaking	2
	Does not respond to mild prodding or shaking	1
Speech	Normal	5
	Mild slowing or thickening	4
	Slurring or prominent slowing	3
	Few recognizable words	2
Facial expression	Normal	5
	Mild relaxation	4
	Marked relaxation (slack jaw)	3
Eyes	Clear, no ptosis	5
	Glazed, or mild ptosis (less than half the eye)	4
	Glazed and marked ptosis (half of the eye or more)	3

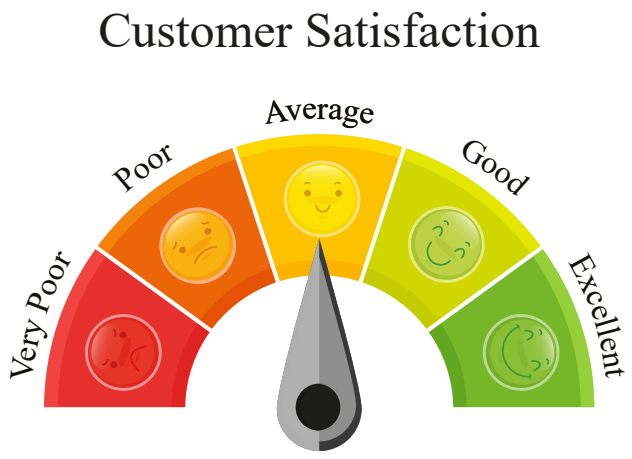

Figure 1 : Likert Scale for satisfaction

Data were analysed using Statistical Package for the Social Science (SPSS) for Windows (version 12.0,SPSSInc,. Chicago, IL, USA). Independent 't' test was used for age, weight, duration of surgery, time for recovery, heart rate, mean arterial pressure and SpO_2 at various time intervals. Chi square test was applied for adverse effects. Paired 't' test was applied for intra-group variation in heart rate and mean arterial pressure. Data were expressed in mean, SD and percentage. P<0.05 was considered to be of statistically significant.

Results:

60 respondents (30 in each group) were included in this randomized clinical trial. The Group KP (Ketofol group) and Group D (Dexmedetomidine group) were found to be comparable in respect of age, weight, duration of surgery (time from surgical incision to surgical closure)(Table I).

There was no significant difference in mean arterial pressure between the two groups before Spinal anaesthesia (baseline), after spinal block, before sedative drug administration and after drug administration (Table II).

There was no significant difference in mean heart rate between the two groups before Spinal anaesthesia (baseline), after spinal block, before sedative drug administration and after drug administration (Table III).

Time of onset of sedation was significantly delayed in Dexmedetomidine group (P<0.001). Duration of sedation i.e. time for arousal from sedation was comparable between the two groups. Percentage of patient satisfied with sedation was not significantly different between the two groups (Table IV).

Incidence of pain in arm during drug administration was significantly more in Ketofol group (P <0.05). Other complications were comparable between the two groups. SpO_2 remained stable throughout the surgical procedure in both the groups, with no statistically significant aberrations (P>0.05) (Table V).

Table I : Demographic data of the patients under study (N=60)

Variable	Group KP(n=30)	Group D (n=30)	P value
Age (years)	30.23±5.3	29.10±4.6	0.381
Weight (kg)	66.51±9.8	67.53±8.7	0.671
Duration of surgery (min)	51.66±4.5	50.65±3.4	0.330

Values are expressed in mean±SD

SD- Standard deviation

N- Total number of participants

n- Number of participants in each group

Table II : Comparison of MAP (mmHg) in study groups at various time intervals (N=60)

Time Interval	Group KP (n=30)	Group D (n=30)	P value
Before Anaesthesia (baseline)	79.1±7.54	80.2±6.88	0.557
After Spinal block	76.3±5.47	75.7±5.43	0.671
Before drug administration	73.7±7.41	74.1±6.42	0.824
After drug administration	72.1±8.41	71.7±8.39	0.854

Values are expressed in mean±SD

SD- Standard deviation

Table III : Comparison of mean heart rate (bpm) in study groups at various time intervals (N=60)

Time Interval	Group KP (n=30)	Group D (n=30)	P value
Before Anaesthesia (baseline)	79.3±9.69	78.4±10.39	0.729
After Spinal block	86.3±11.17	88.1±10.51	0.522
Before drug administration	81.6±11.71	78.6±9.84	0.287
After drug administration	86.5±10.07	81.5±11.18	0.073

Values are expressed in mean±SD

SD- Standard deviation

Table IV : Comparison of Sedation characteristics in study groups (N=60)

Variable	GroupKP (n=30)	Group D (n=30)	P value
Time required for onset of sedation (eye closure) (min)	1.49±0.51	6.54±2.51	<0.001
Arousal time from sedation in min (OAA/S score of 5)	25.3±6.37	26.2±5.38	0.556
Satisfaction with sedation (good)	20 (66.66%)	26 (86.66%)	0.069

Values are expressed in mean±SD

SD- Standard deviation

Table V: Incidence of complications in study groups (N=60)

Variable	Group KP (n=30)	Group D (n=30)	P value
Nausea and Vomiting	5 (16.7%)	4 (13.33%)	0.717
Chills	3 (10%)	2 (6.66%)	0.642
Restlessness	3 (10%)	4 (13.33%)	0.690
Pain in arm	10 (33.33%)	3 (10%)	<0.05
Hypoventilation (↓SpO_2)	6 (20%)	5 (16.7%)	0.743

Discussion

Pregnant women undergoing elective Caesarean sections under Subarachnoid anaesthesia are often anxious about the unpleasant experience associated with awareness during surgery. After being informed about the possible use of sedative after baby extraction, the patients usually more eagerly accept this suggested method of anaesthesia.[2]

The most widely used technique for administering sedation in regional anaesthesia is the intermittent bolus dose technique. This technique has been shown to be associated with peaks and troughs in plasma concentration producing significant side effects and delayed recovery.[9] Continuous infusions have been proved to produce, lesser side effects, faster recovery, easy controllability over the desired depth of sedation but requires some especial equipments e.g. syringe pump, BIS monitor etc, which is expensive and not available everywhere. Moreover, it needs more expertise like interpretation of EEG.[10]

When using sedative medication during regional anaesthesia technique, the anaesthesiologist attempts to titrate the drug to optimize patient comfort while maintaining cardiorespiratory stability and intact protective reflexes. The assessment of depth of sedation has been traditionally performed by observing clinical parameters such as appearance, response to voice, and pain on surgical stimulation. These parameters are qualitative and assessment of response to voice requires patient stimulation, which may itself alter depth of sedation.[11]

We chose the OAA/S scale for assessment of sedation over other scales as it was easier to use, comprehensive and inclusive of parameters such as facial expression and eyelid ptosis in addition to speech and responsiveness, which are not there in other sedation scales.[12] Similarly the OAA/S scale has been shown to have an inter-rater agreement that varies between 85% and 96% depending on the level of sedation, which is higher than most of the other scales used for the same purpose, making it the most suitable choice if precise assessment of sedation is required.[10]

The combination of Ketamine and Propofol (Ketofol) is theoretically expected to have the advantages of both drugs and to complement each other's disadvantages. Haemodynamic compromise induced by Propofol may be compensated by the sympathomimetic effect of Ketamine. Psychomimetic adverse effects are known to be reduced by concomitant use of Propofol. Indeed the combination has been shown to be useful in many clinical situations, with better profiles in haemodynamic stability, respiratory depression, analgesia, and recovery than each agent alone.[13]Dexmedetomidine, a potent and highly selective α 2-adrenoceptor agonist, has been safely used to sedate patients under regional anaesthesia. It induces potent sedation through its action on the locus coeruleus, the predominant brainstem nucleus involved in sleep regulation and respiratory control. Compared to traditional sedatives, patients treated with dexmedetomidine have better arousability and cooperation, minimal respiratory depression, and better postoperative cognitive function. Dexmedetomidine is usually given initially as a bolus, followed by continuous infusion. Single-dose dexmedetomidine can also provide adequate sedation during short procedures under spinal anaesthesia.[14]

Jo et al. conducted a randomized trial on 116 adult patients, who were assigned to receive either midazolam (n=58) or dexmedetomidine (n=58) during spinal anaesthesia. Systolic, diastolic, and mean arterial pressure; heart rate, peripheral oxygen saturation, and bispectral index scores were recorded during surgery, and Ramsay sedation scores and postanaesthesia care unit (PACU) stay were monitored. Hypotension occurred more frequently in the midazolam group (P<0.001) and bradycardia occurred more frequently in the dexmedetomidine group (P<0.001). Mean Ramsay sedation score was significantly lower in the dexmedetomidine group after arrival in the PACU (P=0.025) and PACU stay was significantly longer in the dexmedetomidine group (P=0.003). They concluded that BIS guided dexmedetomidine sedation can attenuate intraoperative hypotension, but induces more bradycardia, prolongs PACU stay, and delays recovery from sedation in patients during and after spinal anaesthesia as compared with midazolam sedation.[15] In our study, haemodynamic effects of Ketofol and Dexmedetomidine were comparable. There was no incidence of bradycardia with dexmedetomidine. Recovery from sedation was comparable between Ketofol and Dexmedetomidine. Duration of PACU stay was not included in our study. Drugs were administered in single dose method in our study.

Hasan HIEA conducted a randomized clinical trial to compare two techniques of moderate sedation for patients undergoing ERCP, using either dexmedetomidine or ketofol as regards haemodynamic, sedation, pain, respiratory effect, recovery time, patients' and endocopists' satisfaction, and complications during and after the procedure. Fifty patients were randomly allocated in one of two groups; dexmedetomidine group D (n=25) received 1mcg/kg i.v. bolus over 10 min followed by 0.5mcg/kg/h or ketamine-propofol (ketofol) group KP (n=25) received 1mg/kg i.v. bolus followed by 50mcg/kg/min. After loading dose, HR (heart rate) and MAP(mean arterial pressure) were significantly lower in group D as compared with group KP (P<0.05). HR was significantly lower in group D during the recovery (P <0.05). No significant difference between both groups as regards time to achieve RSS(Ramsay Sedation Score), MAS(Modified Aldrede Score), FPS (Facial pain scale) and total dose of rescue sedation. Personnel restraint was significantly lower in group KP (8% versus 20%) than in group D. Endoscopists' satisfaction was significantly higher in group KP than D group (92% and 80%) respectively. He concluded that ketofol (1:1) provided better haemodynamic stability than dexmedetomidine and standard alternative to it in moderate sedation during ERCP.[8] In our study, both the drugs were administered in single dose method. Haemodynamic effects of both the drugs were comparable. Patients' satisfaction was comparable between the two drugs. Surgeons' satisfaction was not included in our study.

Akcaalan et al. carried out prospectively a double blind randomized study to compare Propofol and Ketofol for sedation in patients who underwent shoulder arthroscopy under anaesthesia with interscalene and suprascapular block. In group1, Propofol 1mg/kg iv, in group 2, Ketofol 1mg/kg iv was administered. More patients required esmolol in the Ketofol group compared to Propofol group; 71.4% vs 33%, P<0.05. In the absence of esmolol, pulse measurements were statistically significantly higher in the Ketofol group than the Propofol group (P<0.05). The mean values of the SpO_2 measurements were significantly lower in the Ketofol group (P<0.05). No statistically significant difference was determined in respect of the postoperative modified Aldrete Scores (MAS). They concluded that both agents have different superior properties and can be used for sedation.[16] In our study, haemodynamic parameters and SpO_2 were stable with Ketofol. Postoperative recovery scoring was not included in our study.

Gamal et al. conducted a prospective study on evaluation of Ketofol for deep sedation and analgesia in minor painful operations in 90 ASA class I & II patients with age ranging from 1 month up to 75yrs. They received Ketofol in a dose ranging from 0.5mg to 0.8mg/kg per dose given iv. Incremental doses were given according to the duration of operation, using Ramsay Scale of Sedation (RSS). They

1. Classified Specialist in Anaesthesiology. Combined Military Hospital, Chattogram.
2. Graded Specialist in Anaesthesiology. Combined Military Hospital, Chattogram.
3. Graded Specialist in Anaesthesiology. Combined Military Hospital, Chattogram.
4. Professor of Anaesthesiology. East West Medical College and Hospital, Dhaka.

***Corresponding Author:**

Colonel Md Enayet Karim
Classified Specialist in Anaesthesiology
Combined Military Hospital, Chattogram.
Mobile: 01739988644
Email: enayet852@gmail.com

concluded that Ketofol was very effective as a sole agent for painful procedure with a low incidence of side effects as emergence phenomena, hypoxia and transient apnoea. Haemodynamic stability was reported. No nausea or vomiting was reported. Supplemental analgesia for increased pain was not required.[17]In our study, paediatric patients were not included. Haemodynamic stability was also reported with Ketofol in our study. Ketofol also had low incidence of side effects except pain in arm during drug administration.

Ayman et al. conducted a randomized trial to evaluate the use of Ketofol "Ketamine: Propofol mixtures" in two different ratios (1:1 and 1:2) for sedation and analgesia for outpatient transrectal ultrasound prostate biopsy. No reported cases of hypotension or bradycardia were detected in Ketofol groups, while hypotension occurred in 48.6% and bradycardia occurred in 11.4% in propofol group. The incidence of hypoxaemia and the need to perform airway support maneuvers were higher in Propofol group. Patients satisfaction was not different among the groups. No difference was found as regard to postoperative adverse effects or pain on injection to Propofol.[18]In our study, Ketofol contained Ketamine-Propofol in 1:1 ratio only. Haemodynamic stability and patient's satisfaction were also good with Ketofol. Incidence of pain on injection was significantly more with Ketofol compared to Dexmedetomidine.

Study limitations

The intervention was not placebo controlled and blinded to neither clinicians nor patients. Additionally, group sizes were small and it was a single centre study. Consequently the clinical relevance remains undetermined and further studies are necessary to confirm potential benefits between the two drugs.

Conclusion

As duration of sedation was comparable between the two drugs but adverse effects was less with Dexmedetomidine, it is recommended that Dexmedetomidine is a better choice than Ketofol for sedation in single dose technique during Subarachnoid block for Caesarean section.

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Disclosure

There is no conflict of interest.

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