Anaesthesia in Paediatric Patients Undergoing Cardiac Catheterization: Comparison between Dexmedetomidine /Propofol, Fentanyl /Propofol, and Ketamine /Propofol.

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Running title: Dexmedetomidine for paediatric cardiac cath.

Abstract

Background: Interventional paediatric cardiological procedures are widely increasing in both number and varieties. Sedation is required during these procedures to maintain stable conditions, and to maintain spontaneous breathing.

Aim: to analyze and compare the effectiveness of three techniques that can be used for sedation during paediatric cardiac catheterization: Dexmedetomidine /Propofol (D/P), Fentanyl /Propofol (F/P), and Ketamine /Propofol (K/P).

Methods: Thirty paediatric patients, ASA physical status II- III, aged 4-12 yr, and body weight between 12–30 kg, admitted for elective cardiac catheterization were studied. All patients received a standardized monitored anaesthesia care. Propofol bolus of 0.5-1mg/kg over 10 minutes followed by an infusion of 25-75µg/kg/min. For intraoperative sedation, patients were randomized into three groups (n=10): Group (D/P) received Dexmedetomidine bolus of 1µg/kg over 10 minutes followed by an infusion of 0.25-0.75µg/kg/hr, group (F/P) received Fentanyl bolus of 1µg/kg over 10 minutes followed by an infusion of 1-2µg/kg/hr, and group (K/P) received Ketamine bolus of 2mg/kg over 10 minutes followed by an infusion of 1-2mg/kg/hr. The haemodynamic responses and recovery characteristics of the three groups were analyzed and compared.

Results: There were no significant differences between the three groups as regards demographic characteristics, and haemodynamic data. It was noticed that time to full recovery was significantly more rapid in the dexmedetomidine/propofol group. No postoperative complications were reported in any patient in all groups.

Conclusions: It was concluded that the use of Dexmedetomidine in combination with propofol anaesthesia is a safe, practical alternative for paediatric patients undergoing elective cardiac catheterization and may be preferable to Fentanyl/ propofol, and Ketamine/ propofol because of the significantly shorter recovery time, without any haemodynamic or respiratory effects during the procedure.

Key words: Dexmedetomidine; Fentanyl; Ketamine; Propofol; Paediatric Cardiac Cath.

Introduction:

The ideal anaesthetic technique for management of paediatric patients scheduled to undergo cardiac catheterization (cath) should be safe, easy to administer, and provide adequate sedation and amnesia, immobility, cardiovascular stability, and fast recovery without residual complications. The maintenance of spontaneous ventilation without supplemental oxygen is also desirable so that the normal physiology is least altered by the anaesthetic technique [1].

Little has been documented of the different anaesthesia techniques for paediatric cardiac cath. General anaesthesia, a combination of meperidine, promethazine and chlorpromazine, ketamine, as well as opioids have been described but not universally accepted [2].

Ketamine is an agent with a long history of successful use in the cardiac cath suite because it has intrinsic analgesic and amnestic properties, protects airway reflexes, and can be administered by multiple routes of administration, but is associated with hemodynamic alterations, dysphoric emergence reactions, emesis, and a prolonged recovery period [3]. Ketamine is also relatively contraindicated in patients with hypertension, increased intracranial pressure, respiratory tract infection, or underlying neuropsychiatric comorbidities such as seizures or psychoses [4].

Propofol is a substituted phenol (diisopropylphenols) anaesthetic that is associated with smooth induction of, and rapid recovery from anaesthesia. Its pharmacokinetic profile favors administration by continuous intravenous infusion to provide complete anaesthesia. Its safety and efficacy in paediatric patients have been demonstrated in numerous studies. Reported side effects include pain on injection into small veins (which may be prevented by pretreatment with small doses of intravenous lidocaine), respiratory depression, airway obstruction and dose-related decreases in blood pressure and cardiac output [5].

It has been shown that propofol have synergistic hypnotic effects when used in conjunction with other classes of analgesic/sedative agents as barbiturates, benzodiazepines, opioids, and ketamine [6].

Because it is a poor analgesic, propofol usually requires the use of an adjunctive analgesic agent e.g. **Fentanyl** [5].

Propofol is uniquely titratable and unlike ketamine, it has intrinsic anti-emetic properties. It provides for a smooth recovery without dysphoria [7].

Dexmedetomidine is a potent and highly selective α_2–adrenoreceptor agonist. It has sedative-hypnotic, anxiolytic, and analgesic, anaesthetic-reducing and sympatholytic effects. In contrast to other agents, the sedation and analgesia produced by dexmedetomidine are achieved without significant respiratory or haemodynamic compromise. In addition, patients sedated with this agent are well oriented, easily rousable and can respond to instructions from the medical staff [8].

Recently, dexmedetomidine and a small dose of propofol were used successfully to sedate a critically ill infant for MRI [9-10].

The aim of this clinical study was to analyze and compare the effectiveness of Dexmedetomidine /Propofol (D/P), Fentanyl /Propofol (F/P), and Ketamine /Propofol (K/P), for intravenous anaesthesia in paediatric patients undergoing cardiac cath.

Patients and Methods:

After institutional approval and a written informed consent was obtained from parents, 30 male and female paediatric patients, ASA physical status II and III, Aged 4-12 yr and body weight between 12–30 kg, admitted for elective cardiac cath for evaluation of congenital heart disease were included in this study. Children with chromosomal abnormalities or other multiple congenital anomalies, or hepatic or renal dysfunction, were excluded. Patients requiring mechanical ventilation or intravenous inotropic support were also excluded from the study.

During the precatheterization clinic visit, consent was obtained; height, weight, and oxygen saturation were recorded. According to hospital policy, all patients were fasting for at least 2- 4 hours before the procedure, and they arrived in the cath laboratory (lab) with an intravenous catheter in situ.

All children were premedicated when they were with their parents in a room outside the cath lab with IV dose of midazolam *(Dormicum® Roche' Hoffmann-La Roche Ltd.Basel, Switzerland)* 0.1mg/kg over a 5-minute period, given by the attending anaesthesiologist just before the procedure, and then the anaesthesiologist accompanied the child to the cath lab.

On arrival in the cardiac cath lab, and prior to induction of anaesthesia, all patients were connected to slandered monitors that included five leads electrocardiogram, and ECG leads II and V5 were continuously monitored, a noninvasive arterial pressure *(Dinamap, Criticon, CA, USA)*, and a digital pulse oxymetry *(Novametrix,515C, NY, USA)*. Heart rate (HR), mean arterial blood pressure (MAP), respiratory rate (RR) and digital oxygen saturation (SpO2) were recorded every 5 min for the duration of the study.

After the measurement of baseline HR, MAP, RR and SpO2, all patients received atropine 0.01 mg/kg IV. None of the patients was preoxygenated.

For intraoperative somnolence, all patients received a propofol bolus of 1mg/kg *(Propofol 1%, Fresenius Kabi- Deutschland)* over a 10-minute period followed by a propofol infusion between 25-100µg/kg/min. To decrease the likelihood of pain on injection, the propofol emulsion was diluted 1:1 with 5% dextrose solution, and the induction dose was preceded by intravenous lidocaine (0.1 ml/kg of a 0.1% solution).

For intraoperative sedation and analgesia, patients were randomized into Three groups (n=10). **The three groups were as follow:**

I : ***Group (D/P):*** Received dexmedetomidine *(Precedex®, 100µg/ml, Abbott Laboratories, North Chicago-USA)* bolus of 1µg/kg over a10-minute period followed by a dexmedetomidine infusion between 0.25-0.75µg/kg/hr.

II: ***Group (F/P):*** Received fentanyl *(Fentanyl – Janssen Pharmaceutica, N.V. Belgium)* bolus of 1µg/kg over a10-minute period followed by a fentanyl infusion between 1-2µg/kg/hr.

III: ***Group (K/P):*** Received ketamine *(TEKAM®50, HIKMA pharmaceuticals, Amman-Jordan)* bolus of 1mg/kg over a10-minute period followed by a ketamine infusion between 1-2mg/kg/hr.

Ramsay scale for sedation [11] (Table 1) was used to assess the onset of a good level of sedation (score of 4-5), at which the procedure can be started.

After induction of somnolence and sedation, children were positioned, prepared, and draped. Local anaesthetic was infiltrated over the femoral vessels to allow cannulation.

At positioning, and cannulation, patient response was assessed using the ***Three-tier observational scale for patient responses*** [12] described in (Table 2).

In all cases, if the patient had marked or moderate response to local anaesthetic, positioning or cannulation (any distress, movement or crying), the additional medications were propofol 0.5 mg/kg given IV via pump over 30 sec., and the infusion rate of propofol and the study sedative drug was increased by 50%. Total doses of the study sedative drug and total dose of propofol were calculated, and when more than 10 boluses of propofol were used, propofol infusion was increased up to a maximum of 100µg/kg/min.

The patients were observed for the cardiorespiratory effects of propofol, and any 10% changes (from the awake baseline value) in HR, MAP, RR, or SpO2 were recorded.

The results of arterial blood gas analyses were recorded whenever they were performed.

If hypoxia (10% decreases in SpO2 from the awake baseline value) was persistent for more than 1 min, patients were put to breathe 30% oxygen in air spontaneously via a transparent face mask. If apnea for more than 15 sec was noticed, breathing was assisted manually with a Jackson-Rees T-piece system.

Haemodynamic catheterization consisted of either arterial or venous cannulations, or both, as well as of shunt and pressure measurements, and at least two different angiograms.

Anaesthetic drug infusions were discontinued when the groin bandage had been applied and the duration of the anaesthetic and total drug doses were recorded. Any adverse effects noted were also recorded.

Postanaesthesia recovery scores, modified from ***Steward*** [13] (Table 3)**,** were determined by an independent blinded observer from the time the infusion was stopped until discharge from the recovery room. Time spent in the recovery area was also noted.

After a minimum of 2 hours on the floor, a final interview with patients and parents was conducted, and then feeding was allowed without restriction. Difficulties with feeding or voiding on the postoperative day were documented.

Statistical Analysis:

The results are reported as mean values ± standard deviations (SD). Nominal data were compared between the three groups by using Fisher's exact probability test. Haemodynamics and recovery data were analyzed with repeated-measures analysis of variance (ANOVA) to compare changes within each group and paired Student's t-test to compare different group data. Significance was $P < 0.05$.

Results:

All patients completed the study protocol, and as regards the demographic characteristics, there were no statistically significant differences in the mean age, or weight of patients, sex distribution, ASA physical status, duration of catheterization, and baseline SpO2 on room air among the three groups as seen in (Table 4).

The response of the patients to positioning, subcutaneous injection of local anaesthetic and cannulation was very similar in all groups using the three-tier observational scale for patient responses [Figure 1].

During cannulation, minimal or no response was observed in 3 patients in fentanyl group, 2 patients in dexmedetomidine group, and 1 patient in ketamine group.

Depending on body weight, duration of catheterization, and number of additional doses of sedation and analgesia, the total doses of propofol throughout the procedure, total doses of propofol throughout the procedure per kilogram body weight, and total doses of propofol per kilogram body weight per hour are presented in (Table 5). Also, total dose of the study drug throughout the procedure, total dose of the study drug throughout the procedure per kilogram body weight, and total dose of the study drug per kilogram body weight per hour are presented in (Table 5).

Additional doses of analgesia and sedation with propofol were required by a higher percentage of patients in the dexmedetomidine / propofol group, then patients in the fentanyl/ propofol group.

Supplemental use of propofol was less frequent in the ketamine group. Mean dose of propofol in the ketamine group was 11±6 mg/kg (6±1mg/kg/hr) which was significantly lower ($P < 0.05$) than the other two groups: - in the dexmedetomidine group it was 18±3 mg/kg (9±2mg/kg/hr), and in the fentanyl group it was 14±7 mg/kg (7±3mg/kg/hr).

As regard haemodynamic data [Figure 2 :(1-4)], there were no clinically significant changes in HR or MAP over time or between groups. However, the number of patients experiencing MAP decreases > 10% (compared to baseline) during induction was significantly higher in the fentanyl/ propofol group, and the number of patients experiencing HR increase > 10% during induction was significantly higher in the ketamine/ propofol. Several patients in the ketamine/ propofol group had episodes of increased HR and MAP, but the frequency of these was not significantly different between the groups, and no interventions were required to treat changes in HR or MAP.

During administration of medication, RR and SpO2 had a small decrease in several patients in the fentanyl/ propofol group and there was arterial desaturations > 5% in SpO2 (compared to baseline) during induction of anaesthesia in this group, whereas none in the dexmedetomidine / propofol, and ketamine / propofol groups showed this degree of change in RR and SpO2. All of the episodes of desaturation, however, occurred on induction concomitantly with a transient decrease in blood pressure. There were no arterial desaturations > 10% in either group.

One patient required jaw thrust and another required oxygen by face mask for decreased SpO2, both in the fentanyl/ propofol group.

Using recovery scoring system modified from Steward (Table 3), it was noticed that time to full recovery was significantly more rapid in the dexmedetomidine/propofol group. The individual Steward scores for complete recovery of consciousness, airway reflexes, and motor function were achieved significantly more rapidly in the dexmedetomidine / propofol group compared with the other two groups (Table 6).

No postoperative complications were reported in any patient in all groups. There were no episodes of apnea, airway obstruction, or emesis in any patient. The patients in the propofol group did not experience any myoclonus or thrombophlebitis. There were no episodes of emergence delirium or unpleasant dreams in the ketamine group.

Parental satisfaction was greater with the dexmedetomidine / propofol group because children sedated with these agents are well oriented, easily rousable and had fast recovery.

Discussion:

Sedation of children undergoing cardiac catheterization was first described by ***Smith et al,1958*** [14] , by using "ataractic mixture" which was an intramuscular IM injection of a mixture of meperidine, promethazine, and chlorpromazine (DPT) and it was called "the lytic cocktail or the cardiac cocktail". IM DPT became the standard sedative for paediatric cardiac cath and for a variety of other procedures in children.

Major shortcomings of DPT include its painful route of administration, slow onset, prolonged effect, lack of reliable amnesia, and frequent occurrence of restlessness. [14] Despite these shortcomings, their "cardiac cocktail" filled a need at the time.

Respiratory depression is a common, dose-related side-effect of opioids. Respiratory depression often reflects excess sedation; however, deep sedation is not reliably achieved with DPT. ***Terndrup et al, 1991*** [15] reported a 29% failure rate for emergency department procedures. Prolonged duration of sedation from DPT was also reported in the same study, in which 19 ± 15 h passed before return to normal behavior. These and other problems have led to calls for "rational and safe alternatives", and the American Academy of Pediatrics Committee on Drugs has issued a critical "reappraisal of lytic cocktail". [2]

Ketamine infusions have long been used to produce sedation and analgesia in pediatric patients undergoing diagnostic or therapeutic procedures in radiology suites and cardiac catheterization laboratories. However, ketamine is associated with a prolonged recovery period and emergence delirium. In addition, ketamine is often avoided in patients with tachycardia or hypertension, and its effects on pulmonary vascular resistance are controversial. [16]

Propofol is an intravenous anesthetic that is noteworthy for rapid emergence. A potential disadvantage of propofol infusions is the lack of analgesia at subanaesthetic plasma concentrations. [5] In the current study, fentanyl was added to the induction dose of propofol to produce analgesia.

The results of the current study demonstrated that fentanyl/ propofol was associated with markedly shorter recovery times compared with ketamine/ propofol. These results are not surprising considering previous investigations of the recovery characteristics of propofol and ketamine.

The surprising results in the current study were the effects of dexmedetomidine / propofol, as the anesthetic conditions for performing the cardiac cath were excellent. The children remained motionless, breathing spontaneously, with stable haemodynamics throughout the procedure. Recovery was more rapid than that of fentanyl/ propofol group Table (6). Patients treated with dexmedetomidine behave differently from those treated with fentanyl or ketamine. They demonstrate smooth arousal and less panic reaction at first awakening (spontaneous opening of eyes), and they also appeared to have little pain, fear, or anxiety. These findings were consistent with those reported by ***Young*** [9], and ***Dany Cote***. [17]

Recently, dexmedetomidine was used in children undergoing noninvasive procedures with the conclusion that dexmedetomidine provided effective sedation and represents an alternative sedative choice for this population. [17- 18]

There was a higher incidence of decreased MAP, RR and SpO2 during anesthetic induction in the fentanyl/ propofol group. These episodes were defined as clinically insignificant by the study criteria, and it tended to be transient and required no therapeutic interventions. It is possible that fentanyl was partially responsible for this decrease in RR and SpO2. Other possibility for the reason of this decreases in

SpO2 occurred in the fentanyl/ propofol group is hypotension as it occurred only during hypotensive episodes associated with anesthetic induction. This suggests that the hemodynamic changes caused by propofol may have increased the right-to-left shunt in some patients. Although it was not severe decrease in SpO2 occurred after these episodes, some authors believe that it is prudent to avoid propofol in critically ill pediatric patients presenting for cardiac catheterization. [1]

Propofol can cause respiratory depression with loss of airway tone, necessitating airway interventions [5] but, in this study, no patient had apnea or required the use of assisted ventilation. The routine use of atropine 0.01 mg/kg IV could have reduced the incidence of adverse respiratory events.

Benzodiazepines are frequently administered with ketamine to prevent emergence delirium. In this study, midazolam IV dose of 0.1mg/kg was used as premedication in all patients. [3] Midazolam could have prolonged the recovery period in the current study by two mechanisms: a sedative effect that is additive to ketamine or by delaying ketamine's metabolism. [1]

None of the study patients experienced an aspiration event, or emesis. The incidence of emesis in this study was consistent with the incidence reported in other studies e.g. ***Kogan et al***, [6] who observed a decreased incidence of emesis when propofol was given in conjunction with ketamine.

This study had several limitations; the number of 10 patients in each group was too small to evaluate reliably differences between the three groups. All the patients were low risk without serious co-morbidity.

Also in this study, the combined administration of midazolam contributed to sedation therapy. The use of the Ramsay sedation scale also has some limitations. The scale is a compromise between accuracy, simplicity and ease of use. As a result, most scores do not differentiate between sedation, anxiety, depression and pain, but provide an estimate of overall patient comfort.

Conclusions:

It was concluded that the use of dexmedetomidine in combination with propofol anesthesia is a safe, practical alternative for pediatric patients undergoing elective cardiac catheterization and may be preferable to fentanyl/ propofol, and ketamine/ propofol because of the significantly shorter recovery time, without any hemodynamic or respiratory effects during the procedure.

Although all of the three anesthetic techniques were satisfactory, dexmedetomidine/ propofol anesthesia appears preferable in haemodynamically stable patients with congenital heart disease admitted for cardiac catheterization. However, further assessment of this technique is needed with larger numbers of patients and with more complicated cases of multiple congenital cardiac anomalies.

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(Table 1): Ramsay Scale for Sedation [11]:

Score	*Level of sedation achieved*
1	Patient anxious, agitated or restless.
2	Patient co-operative oriented and tranquil.
3	Patient responds to commands.
4	Asleep but with brisk response to light glabeller tap or loud auditory stimulus.
5	Asleep, sluggish response to light glabeller tap or loud auditory stimulus.
6	Asleep, no response.

(Table 2): Three-tier observational scale for patient responses [12]:

Scale	*Patient Responses*
Marked response	Marked distress, Extreme agitation, Physical resistance, Purposeful movement, Prolonged crying.
Moderate response	Moderate distress, Partial arousal, Nonpurposeful movement, Brief crying.
Minimal or no response	Minimal or no response, Minimal movement of a single extremity, Well tolerated.

(Table 3): Recovery Scoring System Modified from Steward [13]:

Consciousness:	
Awake	3
Responds to verbal stimuli	2
Responds to tactile stimuli	1
Not responding	0
Airway:	
Cough on command or cry	2
Maintains good airway	1
Require airway assistance	0
Motor:	
Moves limbs purposefully	2
Nonpurposeful movements	1
Not moving	0

(Table 4): Demographic data of all groups (mean ± SD):

Parameter	*Group D/P* (n=10)	*Group F/P* (n=10)	*Group K/P* (n=10)
Age (yr)	7.2±2.8	7.3±2.3	7.2±3.1
Weight(kg)	19.2±6.4	19.5±7.6	19.4±8.3
Male/female	6/4	5/5	4/6
ASA class II/ III	8/2	7/3	7/3
Baseline SpO2	87±12	88±11	89±10
Duration of catheterization (min)	109±28	104±31	111±25
Diagnosis :			
- TOF	3	2	2
- TOF + PA	2	2	1
- VSD	2	1	2
-VSD + PH	-	2	1
- VSD + ASD	1	-	1
- ASD	2	1	2
- PDA	-	2	-
- TA	-	-	1

No significant difference between the three groups. D= Dexmedetomidine, P= Propofol, F=Fentanyl, K= Ketamine, SpO2= digital oxygen saturation, TOF= tetralogy of Fallot, PA= pulmonary artesia, VSD= ventricular septal defect, PH= pulmonary hypertension, ASD= atrial septal defect, PDA= patent ductus arteriosus, TA= tricuspid artesia.

(Table 5): Doses of drugs used in all groups during the procedure (mean ± SD):

Parameter	*Group D/P* (n=10)	*Group F/P* (n=10)	*Group K/P* (n=10)
Weight(kg)	19.2±6.4	19.5±7.6	19.4±8.3
Duration of catheterization (mg)	109±28	104±31	111±25
Total dose of propofol (mg)	356±34	285±56	231±42
Total dose of propofol /kg (mg)	18±3	14±7	11±6
Total dose of propofol/kg/hr (mg)	9±2	7±3	6±1*
Total dose of study drug	38±3 (µg)	78±9 (µg)	81±5 (mg)
Total dose of study drug /kg	1.9±0.3 (µg)	3.5±1.2(µg)	4.5±1.6 (mg)
Total dose of study drug /kg/hr	1±0.2 (µg)	1.8±0.4(µg)	2.4±1.8 (mg)

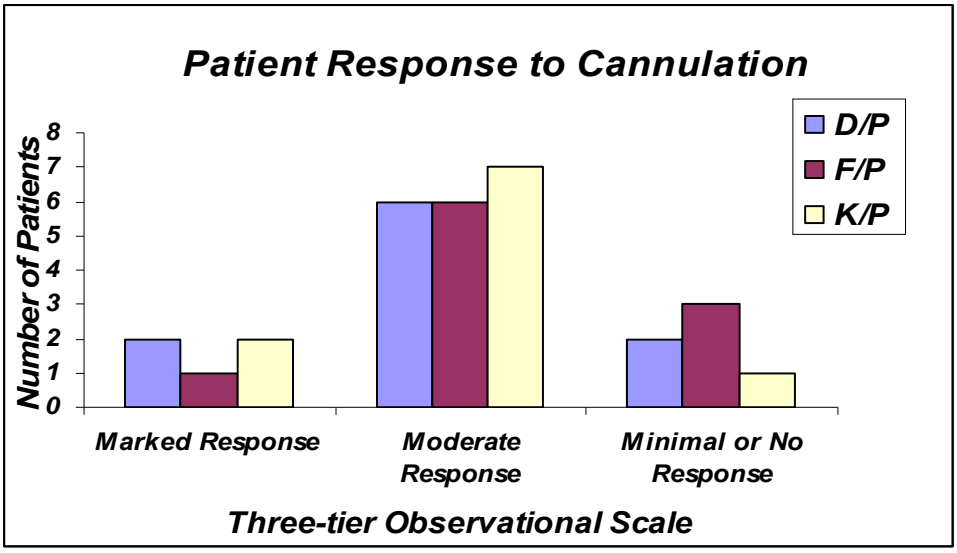
**** Significantly lower than other two groups (P < 0.05).***
D= Dexmedetomidine, P= Propofol, F=Fentanyl, K= Ketamine.

(Table 6): Data of Recovery in all groups (mean ± SD):

Parameter	*Group D/P* (n=10)	*Group F/P* (n=10)	*Group K/P* (n=10)
Time to full consciousness (min)	25±12*	36±14	138±25
Time to airway recovery (min)	15±10*	20±11	111±31
Time to motor recovery (min)	11±8*	18±9	79±38

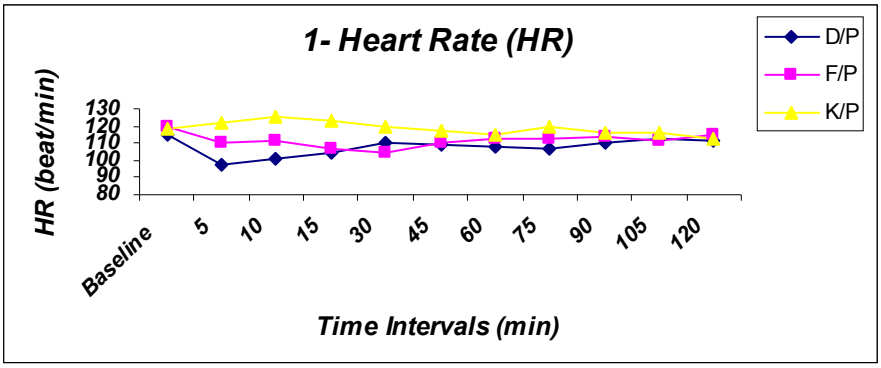
**** Significantly lower than other two groups (P < 0.05).***
D= Dexmedetomidine, P= Propofol, F=Fentanyl, K= Ketamine.

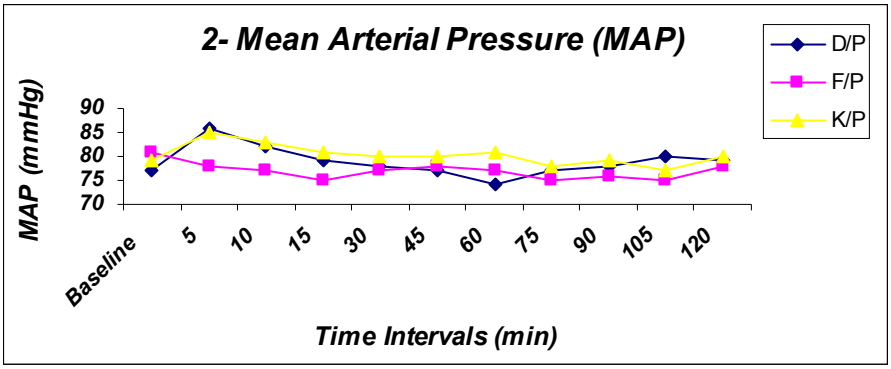
[Figure 1]: Three-tier observational scale for patient responses.

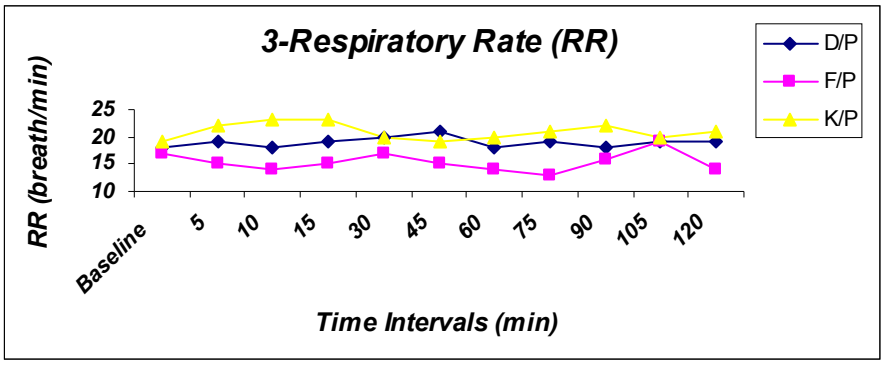


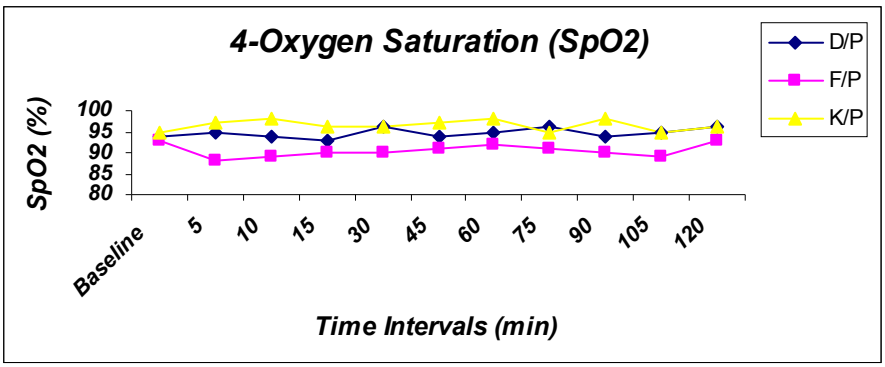
D= Dexmedetomidine, P= Propofol, F=Fentanyl, K= Ketamine

[Figure 2 :(1-4)] Haemodynamic changes in all groups.









D= Dexmedetomidine, P= Propofol, F=Fentanyl, K= Ketamine.
No clinically significant difference between the three groups.