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Comparison of IV dexmedetomidine & propofol versus IV dexmedetomidine & ketamine for daycare urological procedures: a randomized controlled study

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Abstract
Background: Most urologic surgeries are performed in a narrow, limited space with minimally invasive technique or cystoscope& anaesthesia for these procedures is administered with the goals of safety, satisfactory procedural condition for the performance of therapeutic or diagnostic procedures ensuring rapid recovery with minimal post-operative complications. Therefore, we decided to compare the efficacy & safety of IV Propofol @1.5 mg/kg +Dexmedetomidine @1µg/kg versus IV Ketamine @ 1mg/kg + Dexmedetomidine @ 1µg/kg in providing procedural sedation in urological procedures.
Material & Methods: This prospective randomized study was conducted in Department of Anaesthesiology of Mamata medical hospital. In this study 50 patients scheduled for elective daycare urological procedures were included and divided equally in two groups. Group A-received IV Propofol 1.5 mg/kg, then infusion of Dexmedetomidine@ 1µg/kgand group B-received IV Ketamine 1mg/kg, then Dexmedetomidine@ 1µg/kg.
Results: In our study, there is no significant difference in age, weight, gender. The comparison of mean between two groups after giving dexmedetomidine was statistically significant ($p< 0.05$) in heart rate, SBP, onset, duration of analgesia, VAS & Ramsay scores but DBP & SpO_2 was statistically not significant.
Conclusion: Comparison of baseline & intraoperative hemodynamics, showed that the values were better maintained in Dexmedetomidine + propofol (Group-A) than Dexmedetomidine + Ketamine (Group B). We have concluded that Dexmedetomidine + Propofol combination was superior to Dexmedetomidine + Ketamine, providing early onset of sedation, prolonged analgesia & stable intraoperative hemodynamics.
Keywords: Dexmedetomidine, propofol, ketamine, urological procedures

Introduction

Most urologic surgeries are performed in a narrow and limited space with minimally invasive technique or cystoscope and most patients undergoing urologic surgeries are individuals with other diseases. Therefore, anesthesiologists should provide adequate anesthesia, consider various factors such as age, co-morbidities, functional status, duration of surgery and surgical scope, to optimize surgical outcomes. Performing them on an outpatient basis would have significant implications on conserving financial and workforce resources, but they must be tolerable[1].

The pain, restlessness and movements of the patient that may lead to complications and the necessity to abort the procedure can be resolved by providing sedation combined with analgesia/anesthesia, usually induced by an anesthesiologist. Anesthesia in urological procedures is administered with dual goals of rapidly and safety establishing, satisfactory procedural condition for the performance of therapeutic or diagnostic procedure while ensuring rapid predictable recovery with minimal post-operative sequel[2].

Dexmedetomidine is a highly selective α2 adrenergic agonist, besides its sedative effect, it

also displays analgesic efficacy. It has minimal respiratory depression which is an important advantage, disadvantage including bradycardia and hypotension. It attenuates but not completely abolishes stress-induced sympatho-adrenal responses protecting the patients from noxious sympathetic stimulation and hemodynamic changes[3].

Propofol –a non-barbiturate sedative & hypnotic. Its effects are mediated by the gamma amino butyric acid (GABA) receptor. It is highly lipophilic and therefore quickly crosses the blood–brain barrier, providing early onset of action and rapid recovery. The main disadvantage of propofol is respiratory and cardiovascular depression[4].

Ketamine, is a phencyclidine derivative & an N-methyl-D-aspartate (NMDA) receptor antagonist is a dissociative anaesthetic with analgesic properties. It maintains airway muscle tone[5].Despite its obvious advantages over other agents, some practitioners are hesitant to use ketamine alone secondary to its ability to cause frightening emergent reactions, sympathomimetic effects, vomiting and excessive salivation even when administered in sedating doses[6].

In this study, we aimed to compare the efficacy of dexmedetomidine + propofol mixture and dexmedetomidine + ketamine among the patients undergoing sedation for the daycare urological procedures. Primary objective was to compare the hemodynamic parameters such as onset of analgesia, Heart rate - Systolic BP, diastolic BP, respiratory rate, SpO_2 at baseline, 5,10,15,20 and 30 mins. Secondary objective was to compare the Duration of analgesia, VAS score and Ramsay sedation score.

Material & Methods

The study was conducted after obtaining approval of the institutional ethics committee, 50 patients were randomly allocated into two groups of 25 each.

Inclusion criteria

1. Patients who gave informed consent.
2. Age between 18-60 years.
3. ASA I & II.

Exclusion criteria

1. Patients with allergy to study drugs.
2. Patients with cardiovascular disease.
3. Ongoing beta blocker therapy.
4. Uncontrolled diabetes & hypertension.
5. Renal & hepatic insufficiency.

50 patients were sufficient to ensure power 80% for detecting clinically meaningful attenuation of heart rate, SpO_2, SBP, DBP changes by 10-20%.

$$n_i = 2\left(\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{ES}\right)^2$$

Where n_i is the sample size required in each group (i= A,B), α is the selected level of significance and Z 1-α /2 is the value from the standard normal distribution holding 1- α/2 below it, and 1- β is the selected power and Z 1-β is the value from the standard normal distribution holding 1- β below it. ES is the effect size.

On the day of the surgery after entering the OT, standard monitoring modules (NIBP, pulse oximetry &ECG) were attached to the patient. Intravenous access was established with 20G cannula, Ringer lactate was started @ 100ml/hr. preoperative vitals were recorded & Premedicated with Inj.Glycopyrrolate 0.02mg/kg, Inj.Midazolam 0.02mg/kg.

Group A: Received Inj. Propofol 1.5 mg/kg intravenous bolus as a loading dose then infusion

of Inj. Dexmedetomidine with a concentration of 0.004 mg/ml as a loading dose of 1 μg/kg for the first 10 min then 0.6 to 1μg/ kg/h to keep the patient sedated with Ramsay sedation score of more than 4.
Group B: Received Inj. Ketamine 1mg/kg intravenous bolus as a loading dose and maintenance of sedation done by Inj. Dexmedetomidine infusion with a concentration of 0.004 mg/ml and infusion rate 1μg/kg for the first 10 min then 0.6 to 1 μg/kg/h to keep the patient sedated with a Ramsay sedation score of more than 4.

Assessment

Systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation (SpO2) were evaluated at 5,10,15,20,30 mins. Duration of analgesia and onset of analgesia, Ramsay sedation score and VAS scores were also evaluated.
Data were analysed using IBM SPSS Advanced Statistics version 23.0 (SPSS Inc., Chicago, IL). Numerical data were expressed as mean and standard deviation. Qualitative data were expressed as frequency and percentage. For quantitative data, comparison between two groups was done using independent sample t-test or Mann-Whitney test. A p-value <0.05 was considered significant.

Results
There was no significant difference in age, weight, gender, ASA and duration of procedure between the groups (p>0.05). The results were shown in table 1.

Table 1: Demographic and clinical characteristics among the groups

Parameters	Group A(n = 25)	Group B(n = 25)	p value
Age (years)	52.7 ± 8.7	51.0 ± 10.7	0.067
Weight (kg)	60.7 ± 8.5	61.8 ± 9.7	0.687
Sex (male/female)	20/10	16/14	0.292
ASA (II/III)	24/6	26/4	0.674
Duration of the procedure (min)	30.3 ± 8.2	24.5 ± 7.5	0.134

Heart rate

There was no significant difference in the baseline heart rate between the groups (p=0.56). Meanwhile, at 5, 10, 20 and 30 mins the heart rate was significantly lower in group A as compared to the Group B post sedation. The results were shown in table 2.

Systolic blood pressure
There was no significant difference in the baseline systolic blood pressure between the groups (p=0.65). Further, the SBP was significantly lower at 5mins (p=0.005), 10mins (p=0.002) in group A as compared to the group B. Meanwhile, at 20 and 30 mins there was no significant change in SBP between the groups. The results were shown in table 3.

Diastolic blood pressure
There was no significant difference in the systolic blood pressure between the groups at baseline, 5, 10, 20 and 30 mins. The results were shown in table 4.

Saturation of peripheral oxygen
There was no significant difference in the SpO2 between the groups at baseline, 5, 10, 20 and 30 mins. The results were shown in table 5.

Onset of analgesia
The onset of analgesia was significantly faster in Group A as compared to Group B and it was significant (7.56±0.76 vs 11.86±1.2 mins; p=0.000). The results were shown in table 6.

Duration of analgesia

The duration of analgesia was significantly prolonged in Group A as compared to Group B and it was significant (281.76±6.56vs 205.65±4.12mins; p=0.002). The results were shown in table 7.

Visual analogue scale score

The mean baseline VAS score (5.12±0.37 vs 5.45±0.65; p=0.34) and at 5 mins (0.7±0.17 vs 0.68±0.15; p= 0.62) was not significant between the GroupA and Group B. Meanwhile, the VAS score was significantly lower in Group A at 10 mins (p=0.03), 20 mins (p=0.002) and 30 mins (p=0.000) as compared to the group B. The results were shown in table 8.

Ramsay sedation score

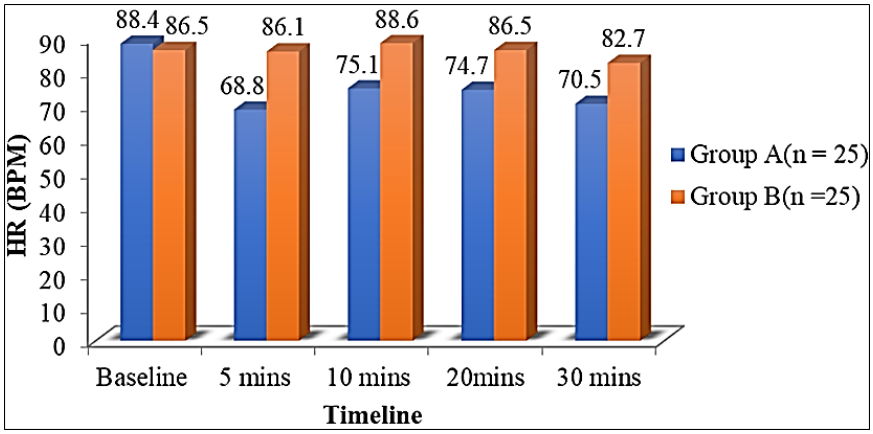
The mean baseline Ramsay sedation score was not significant between the Group Aand Group B (5.12±0.37 vs 5.45±0.65; p=0.45). The Ramsay sedation score of 3 was significantly achieved in 3 mins in group A as compared to group B, where in 5 mins only a mean score of 2.34 (p=0.020). Meanwhile, Ramsay sedation was significantly higher in group A at 10mins (p=0.04), 20 mins (p=0.02) and 30 mins (p=0.01) as compared to the group B.

Heart rate

Table 2: Comparison of mean heart rate between the groups

Heart rate (BPM)	Group A(n = 25)	Group B(n =25)	P value
Baseline	88.4±17.7	86.5±16.1	0.56NS
5 mins	68.8±16.3	86.1±15.8	0.000*
10 mins	75.1±17.8	88.6±16.5	0.000*
20mins	74.7±16.8	86.5±15.1	0.007*
30 mins	70.5±12.4	82.7±14.24	0.002*

The data are represented as mean ± SD. *denotes p value < 0.05. NS-Non-significant.

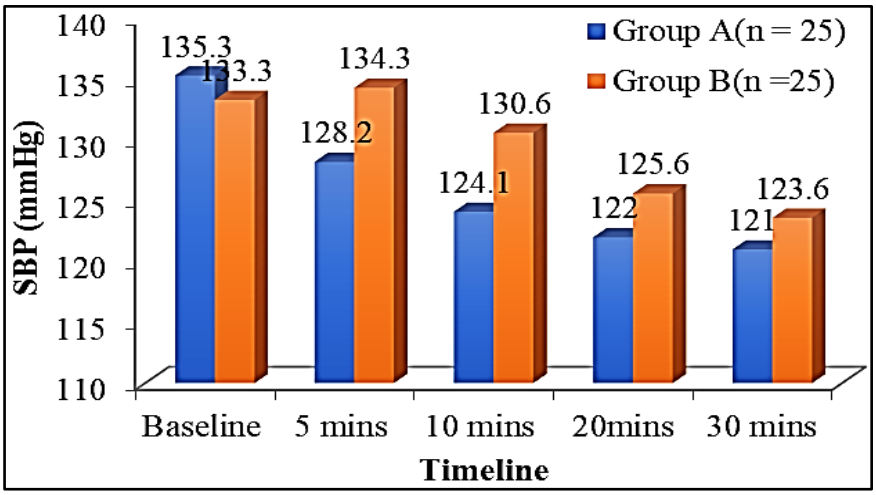


Systolic blood pressure

Table 3: Comparison of systolic blood pressure between the groups

Systolic blood pressure (mmHg)	Group A(n = 25)	Group B(n =25)	P value
Baseline	135.3±18.0	133.3±15.4	0.65NS
5 mins	128.2±14.7	134.3±20.6	0.005*
10 mins	124.1±18.5	130.6±13.6	0.002*
20mins	122.0±19.2 8	125.6±15.	0.08NS
30 mins	121.0±18.56	123.6±12.76	0.12 NS

The data are represented as mean ± SD. *denotes p value < 0.05. NS-Non-significant.

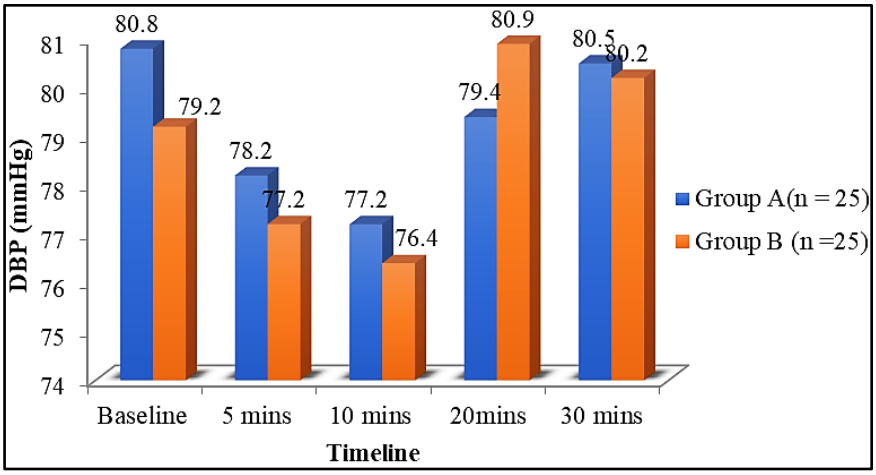


Diastolic blood pressure

Table 4: Comparison of diastolic blood pressure between the groups

Diastolic blood pressure (mmHg)	Group A(n = 25)	Group B (n =25)	P value
Baseline	80.8±14.6	79.2±11.0	0.65 NS
5 mins	78.2±14.8	77.2±11.1	0.78 NS
10 mins	77.2±15.7	76.4±11.3	0.62 NS
20mins	79.4±13.7	80.9±13.3	0.71 NS
30 mins	80.5±14.65	80.2±15.25	0.76 NS

The data are represented as mean ± SD. *denotes p value < 0.05. NS-Non-significant.



Saturation of peripheral oxygen

Table 5: Comparison of SpO_2 between the groups

Peripheral oxygen saturation (SpO_2)	Group A(n = 25)	Group B(n =25)	P value
Baseline	97.8±1.7	98.0±2.2	0.24NS
5 mins	96.5±5.1	94.8±10.1	0.75 NS
10 mins	96.1±4.7	95.4±8.1	0.42 NS
20mins	97.6±2.3	98.1±1.6	0.65 NS
30 mins	98.2±2.5	98.8±1.8	0.81 NS

The data are represented as mean ± SD. *denotes p value < 0.05. NS-Non-significant.

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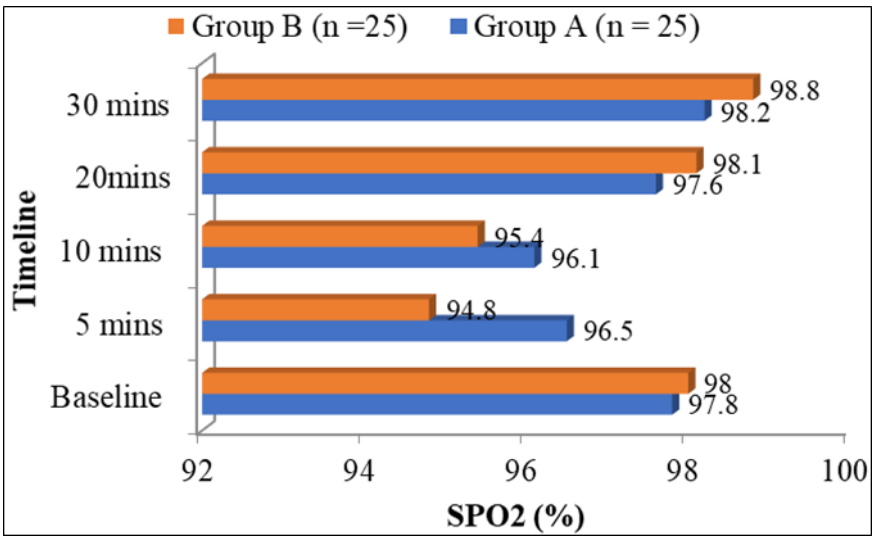
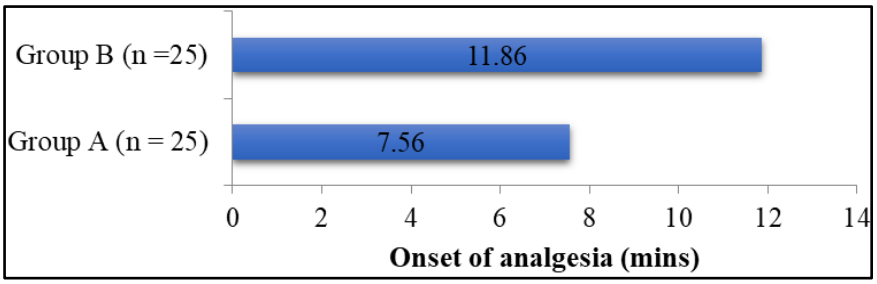


Onset of analgesia

Table 6: Comparison of onset of analgesia between the groups

Parameter	Group A(n = 25)	Group B(n =25)	P value
Onset of analgesia (mins)	7.56±0.76	11.86± 1.2	0.000*

The data are represented as mean ± SD. *denotes p value < 0.05. NS-Non-significant.

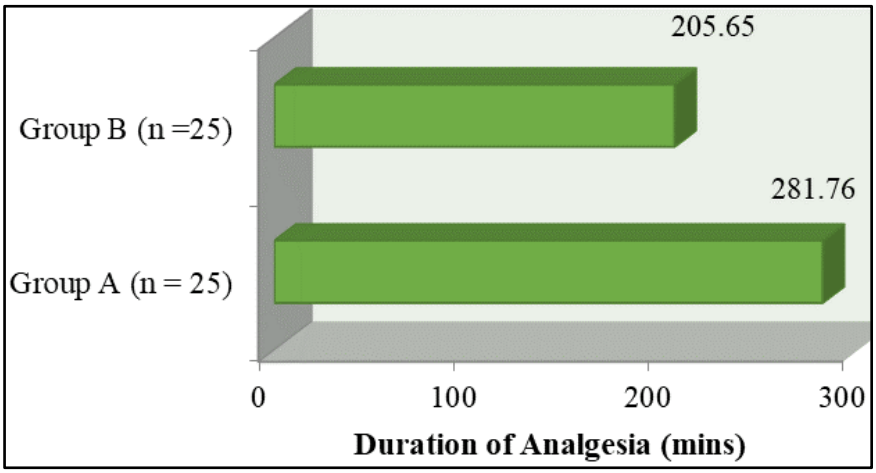


Duration of analgesia

Table 7: Comparison of duration of analgesia between the groups

Parameter	Group A(n = 25)	Group B (n =25)	P value
Duration of analgesia (mins)	281.76±6.56	205.65±4.12	0.002*

The data are represented as mean ± SD. *denotes p value < 0.05. NS-Non-significant.



Visual analogue scale score

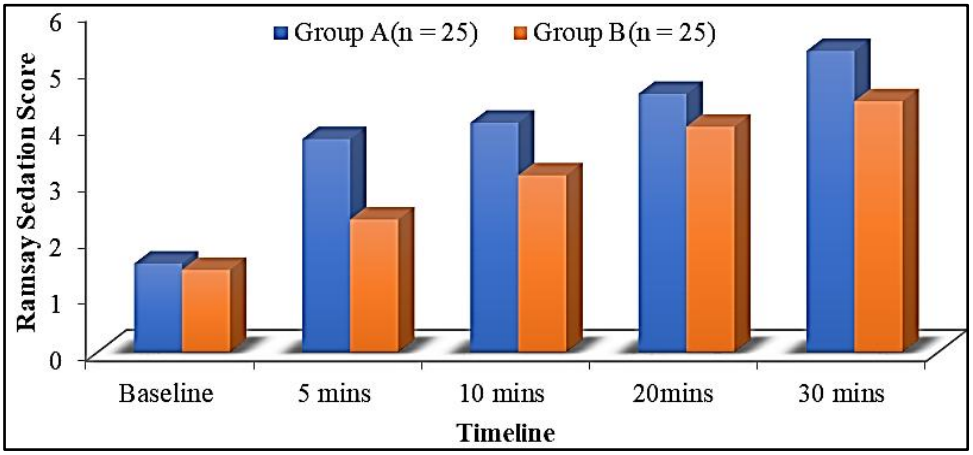
Table 8: Comparison of VAS scores between the groups

VAS Score	Group B(n = 25)	Group A(n =25)	P value
Baseline	5.12±0.37	5.45±0.65	0.34NS
5 mins	0.7±0.17	0.68±0.15	0.62 NS
10 mins	1.84±0.33	1.12±0.24	0.03 *
20mins	2.43±0.30	1.78±0.21	0.002 *
30 mins	3.04±0.39	2.68±0.24	0.000*

Ramsay sedation score

Table 9

Ramsay sedation score	Group A(n = 25)	Group B(n = 25)	P value
Baseline	1.56±0.05	1.45±0.07	0.45NS
5 mins	3.76±0.08	2.34±0.09	0.02*
10 mins	4.05±0.8	3.12±0.9	0.04*
20mins	4.56±1.12	3.98±0.8	0.02*
30 mins	5.32±1.34	4.43±0.9	0.01*



Discussion

The importance of sedation has increased with the widespread use of urological procedures. This study compared the effectiveness and reliability of two different moderate sedation regimens. Results suggested that the use of dexmedetomidine propofol or dexmedetomidine ketamine during the urological procedures such as cystoscopy may be appropriate and safe. The combination of dexmedetomidine-propofol has been highlighted because of its better stable hemodynamics, better sedation level, preservation of saturation and fewer side effects. An ideal agent for sedation during urological procedures should have rapid onset, quick recovery and few side effects. However, today there is no ideal agent with all these features. The present study aimed to identify a near-ideal agent for urological procedures. It is known that propofol can induce arterial hypotension and respiratory depression due to sympathetic nervous system inhibition and direct vasodilator effects[7].Dexmedetomidine provides adequate analgesia, better hemodynamic stability and does not cause respiratory depression at therapeutic doses. In the present study, dexmedetomidine was combined with propofol to create ideal sedation levels and provide rapid recovery. Due to the sympatholytic effects of both agents, the combination was worrying, but sedation was achieved with a fairly stable hemodynamicsa suitable depth, onset of analgesia was faster. Further, the duration of analgesia was significantly more in Dexmedetomidine-propofol as compared to Dexmedetomidine- ketamine[8].Further, the VAS scores were lower in dexmedetomidine-propofol and to achieve the Ramsay sedation score of 3-4 was earlier in dexmedetomidine-

propofol as compared to Dexmedetomidine-ketamine.The results were in accordance to the study done by Abdellatif and Ibrahim[9] where the patients administered with dexmedetomidine-propofol showed better induction, recovery time, good VAS and Ramsay score as compared to Dexmedetomidine-ketamine during MRI procedures.

Conclusion

The study concluded that dexmedetomidine with propofol combination was superior to dexmedetomidine with ketamine combination in providing early onset of sedation, stable intra operative hemodynamics for daycare urological procedures.

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