

A study of safety and efficacy of dexmedetomidine in cystoscopy**N.Anupama Priyadarshini¹, W.R Pathanjali Rao^{1*}, A. Anuradha², Varshini JS³**¹Associate Professor, Department of Anesthesia, Osmania Medical College, Hyderabad, Telangana, India² Professor, Department of Anesthesia, Osmania Medical College, Hyderabad, Telangana, India³ Second year Postgraduate, Department of Anesthesia, Osmania Medical College, Hyderabad, Telangana, India

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Abstract

Introduction: Outpatient performance of minimally invasive transurethral procedures, such as cystoscopy, will have a substantial effect on the protection of financial and workforce capital, but they must be tolerable. By providing sedation coupled with analgesia/anesthesia, normally induced by an anesthesiologist, the discomfort, restlessness and patient movements that can lead surgeon's discomfort during the procedure can be solved. **Aim:** To study the efficacy and safety of Dexmedetomidine given at a dose of 0.5 µg /kg 10 minutes before cystoscopy. **Material and methods:** Prospective randomized controlled study done at Osmania General Hospital for a period of 2 months in Sixty patients presenting for cystoscopy in urology operation theatre were randomly assigned into two groups either Group-A or Group-B. Results: 0.5 µ/kg of dexmedetomidine was administered 10 minutes prior to the procedure that was not accompanied by maintenance infusion and had no hemodynamic changes along with VAS of 3.78 intraoperatively (mild to moderate pain score) and VAS 2.89 (mild pain) postoperatively compared to the Placebo group sample, in which VAS was 7.2 intraoperatively and postoperatively 4.4 suggesting moderate to severe pain in the group. While in the dexmedetomidine group the OAA/S scale was 5 both intraoperatively and postoperatively indicating patient alertness during and after cystoscopy. **Conclusion:** Dexmedetomidine infusion even without loading dose provides safe, effective adjunct analgesia, without undesirable hemodynamic effects in cystoscopy.

Keywords: Dexmedetomidine, Cystoscopy, Outpatient.

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Introduction

Minimally invasive transurethral procedures, such as cystoscopy, insertion of indwelling urethral stents, bladder biopsies, and fulguration of superficial bladder tumors may be associated with pain and discomfort for patients. Performing them on an outpatient basis would have significant implications on conserving financial and workforce resources, but they must be tolerable. The pain, restlessness and movements of the patient that may lead to surgeon's discomfort during the procedure which can be resolved by providing sedation combined with analgesia/anesthesia, usually

induced by an anesthesiologist. Cystoscopy is a procedure used to diagnose, monitor and treat the conditions affecting the urinary bladder and urethra. During the procedure the urologist introduces the cystoscope (hollow tube with lens) through urethra after applying an anesthetic gel to visualize the lining of the urinary bladder. This procedure is done in lithotomy position (feet in stirrups with knees bent). The patient may feel some discomfort during and after the procedure. Some experience fear and anxiety for undergoing cystoscopy. Dexmedetomidine has been increasingly used as sedative in Monitored anaesthesia care for its analgesic property, cooperative sedation and lack of respiratory depression [1,2]. By administering anxiolytic and analgesic which does not cause respiratory depression eases the patient of any pain or discomfort thus also provides the surgeon comfort while doing the procedure. Although cystoscopy is a

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quick procedure some patients feel discomfort and anxious during and after the procedure. By administering inj. Dexmedetomidine which is an analgesic, anxiolytic and sedative with out respiratory depression patient's discomfort are reduced which also facilitates surgeons comfort during the procedure. Here we study the analgesic, anxiolytic property and recovery of Dexmedetomidine. To study the efficacy and safety of inj. Dexmedetomidine in cystoscopy which would provide good analgesia, thus obliterating discomfort during the procedure.

Materials & methods

Prospective randomized controlled study done at Osmania General Hospital for a period of 2 months from August 2020 to September 2020. Random Allocation Software is created in Microsoft Visual Basic 6, and it were used to allocate patients to one of the two study groups with an allocation ratio of 1:1. Patient randomisation were done after enrollment in the study by us and random sequence will be generated and opened by the default viewer for the output file. Sixty patients presenting for cystoscopy in urology operation theatre were randomly assigned into two groups either Group-A or Group-B. Group-A receive inj.normal saline 5 ml as placebo before the procedure.

Group B receive inj.Dexmedetomidine 0.5 μ /kg diluted in 5ml distilled water 10 minutes before the procedure.

Inclusion Criteria

- Patients undergoing cystoscopy procedure belonging to ASA grade I & grade II.
- Age between 18 -60 yrs.
- Patients with written consent.

Exclusion criteria

- ASA grade III & grade IV.
- Age <18 to >60 yrs.
- Patients on anticoagulants, immunosuppressive drugs, with bleeding disorders and urinary tract infections.
- Patients who do not give consent.

Methodology: All patients will be assessed in pre anaesthetic clinic. In the operating room all basic monitors will be connected and preop vitals are noted. Group-A will receive 0.9% normal saline in 5cc syringe.intraop vitals will be monitored. Visual analogue scale measurement and Observers Assessment of Alertness/Sedation score OAA/S is noted. post op vitals was monitored. Group-B after noting preop vitals inj.dexmedetomidine 0.5 μ g/kg diluted in a 5cc syringe is administered to the patient 10 minutes before procedure. Intra op vitals along with VAS, and OAA/S was noted.Post-op vitals, VAS and OAA/S noted in immediate post-op and for every 5 min for a duration of 30 min is noted for group-B .

Table 1: Modified Observer's Assessment of Alertness/Sedation Scale

Score	Responsiveness
5	Responds readily to name spoken in a normal tone
4	Lethargic response to name spoken in a normal tone
3	Responds only after name is called loudly and /or repeatedly
2	Responds only after mild prodding or shaking
1	Responds only after painful trapezius squeeze
0	No response after painful trapezius squeeze

Statistical Analysis: The experimental data were expressed as mean \pm Standard deviation. The significance of the differences between treatments and respective controls will be analyzed using the student's t-test using Microsoft excel.

Results: In total 60 patients who are undergoing cystoscopy procedure in urology operation theatre.

Table 2: Details of participants in study

Details	Group-A	Group-B
Age in years	N (%)	N (%)
<24 years	2(6.7)	1(3.3%)
25-34 years	8(26.7%)	9(30%)
35-44	4(13.3%)	3(10%)

45-54	7(23.3%)	6(20%)
>55	9(30%)	11(36.7%)
Gender		
Males	18(60%)	17(56.7%)
Females	12(40%)	13(43.3%)

Patient characteristics are not significant when compared in 2 groups.

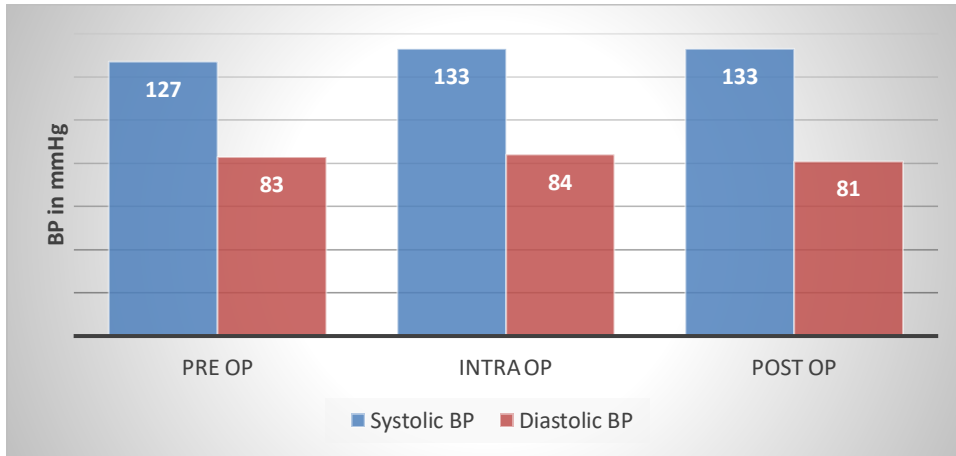


Fig 1: Blood pressure in group-A(in placebo group)

Systolic blood pressure are significant in group-A patients between preop and intraop also significant in preop and post op.

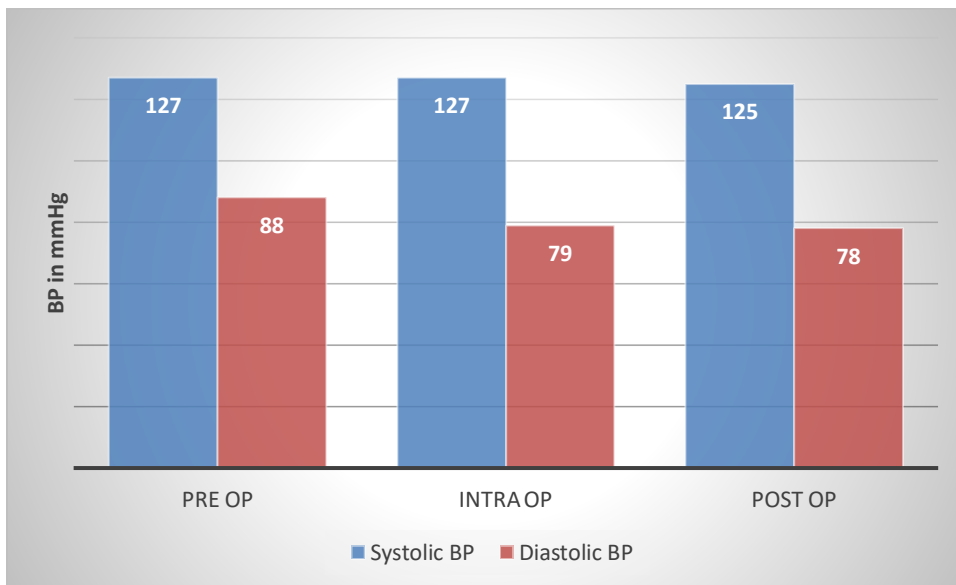


Fig 2: Blood pressure in Group-B(Dexmedetomidine group)

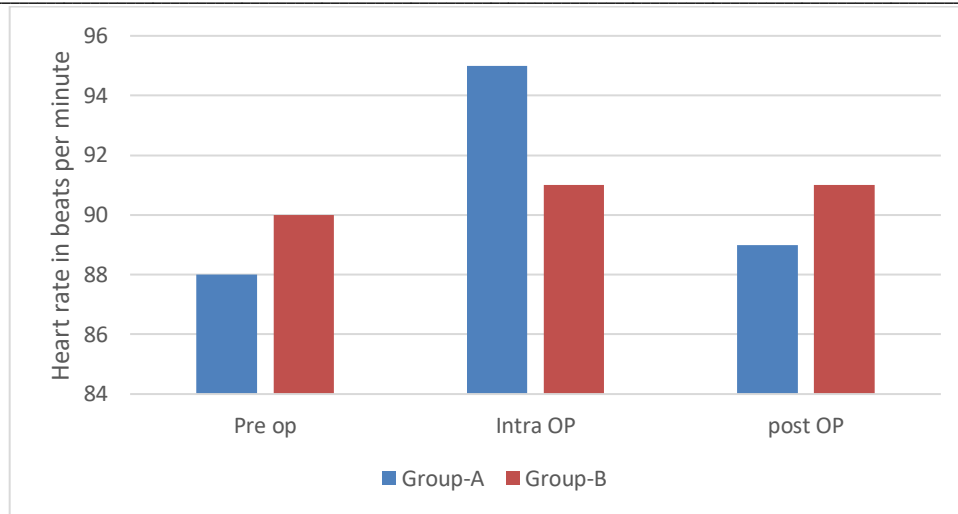


Fig 3: Pulse rate in both groups

Systolic and Diastolic blood pressure are insignificant between all groups. Pulse rate is significant between preoperatively compared to intraop in Group-A and were as insignificant in all other groups. Oxygen saturation is insignificant in all groups.

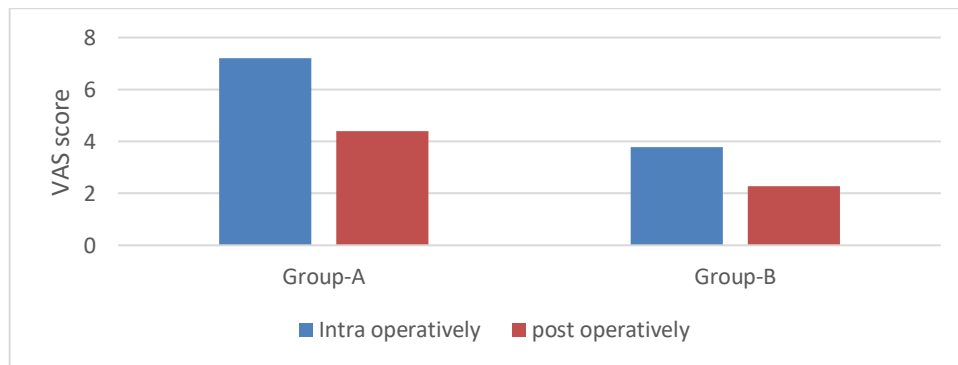


Fig 4: Mean VAS score comparison in both groups

Dexmedetomidine treated patients had significantly less VAS score at each level ($P < 0.001$). In group B OAA/S In both intraoperative and post op is 5 All patients in Modified observer's assessment of alertness/sedation score is 5, so all patients of group-B are alert.

Discussion

When used for procedural sedation, dexmedetomidine preserves airway stability. Previous reports identify dexmedetomidine given in doses up to 10 µg/kg to promote airway surgery[10]. While a loading dose of 1.0 µg/kg accompanied by a maintenance infusion of 0.2 to 1.0 µg/kg/hr is recommended in the approved product details, 0.5 µg/kg was administered 10 min

before the treatment in this study, which was not followed by maintenance infusion. The current research aims to introduce a very short-term procedure such as cystoscopy to the literature on the safety of Dexmedetomidine when used at doses lower than prescribed. The data from our study where observational trials of non-intubated patients used 0.5 µg/kg doses of dexmedetomidine is done to know sedation scores. In the current placebo group sample, VAS was 7.2 intraoperatively and postoperatively 4.4 suggesting moderate severe pain in the group, while in the dexmedetomidine group VAS was 3.78 intraoperatively and 2.28 postoperatively indicating mild to moderate pain, the OAA/S scale was 5 indicating patient alertness. 0.5 µg/kg of dexmedetomidine was administered 10 minutes prior to

the procedure that was not accompanied by maintenance infusion and had no hemodynamic changes along with mild to moderate pain score compared to distressing pain encountered in cystoscopy. The drug's anxiolytic and sedative properties were evident at this dose. The result of this study is consistent with the previous studies of Mason and colleagues showing their experience with dexmedetomidine for sedation for paediatric nuclear medicine imaging, starting with 2 µg/kg with the option to repeat the bolus twice in order to achieve a present sedation score. In a randomised, double-blinded study involving a small group of participants with stable cardiovascular systems, Hall et al. found that small doses (0.2 and 0.6 µg/kg/h infusions, small and moderate doses, respectively) of dexmedetomidine provided conventional pain treatment with significant sedation and analgesia[3]. Well preserved were both cardiovascular stability and respiratory function. The omission of the dexmedetomidine loading dose was a unique feature in a study by Shehabi et al. on tertiary general ICU patients. In all patients, dexmedetomidine started at 0.4 µg/kg/h and then increased (maximum 0.7 µg/kg/h) or decreased (minimum 0.2 µg/kg/h) every 15 minutes, as considered clinically essential[4]. In the Shio Priye et al randomised controlled trial in 306 patients undergoing cardiac surgery, dexmedetomidine was shown to provide successful sedation and targeted analgesia at a median dose of 0.49 µg/kg/h without an increase in hypotension or vasopressor requirements [5]. In addition, in contrast with the morphine-based regimen, dexmedetomidine therapy significantly reduced the length of delirium and facilitated early extubation. After beginning dexmedetomidine without a loading dose, Ickeringill et al. reported a reduction of 8 percent in heart rate and 10 percent in systolic blood pressure from baseline[6]. With a 50-70 percent decrease in propofol, midazolam and opioid requirements, dexmedetomidine has a clear synergistic effect with other sedatives and opioids[7]. It is well known that dexmedetomidine has opioid-sparing effect[8]. Ickeringill et al. studied without a loading dose in postsurgical patients and found that 76 percent did not need rescue sedation and 48 percent did not need rescue analgesia. 7 cases (14 percent) of those needing rescue analgesia required considerable additional analgesia[6]. The least additional sedation and or analgesia was needed in the cardiac group. Shahbaz et al. concluded that dexmedetomidine administration significantly reduced the early postoperative need for morphine by 66 percent before completion of major surgical procedures associated with above-average postoperative pain and 65 percent

of patients treated with dexmedetomidine did not require any additional analgesia in 1st hour of recovery [9]. The Venn et al. study included 98 patients with full data, 47 with dexmedetomidine, and 51 with placebo[10]. Eighty-one patients (83 percent) had CPB-requiring cardiac surgery. There were no overall variations in the distribution of Ramsay Sedation Scores when intubated between the dexmedetomidine and placebo groups. Shehabi et al. concluded that, as shown by 83 percent of observed RSS reported between 2 and 5 over the study period, most patients had acceptable quality sedation[7]. The overall effect on sedation and analgesia was comparable in magnitude to studies with a clear effect on postoperative surgical patients. Our study was well associated with previous studies. We found that patients treated with dexmedetomidine had less pain and analgesic needs in the postoperative period. Taken together, maintenance with DEX without loading dose shown similar proanalgesic and morphine-sparing effects without hemodynamic alterations, such as bradycardia, induced by DEX loading dose

Conclusion

Placebo group sample, VAS was 7.2 intraoperatively and postoperatively 4.4 suggesting distressing/moderate pain in the group, while in the dexmedetomidine group VAS was 3.78 intraoperatively and 2.28 postoperatively. With a dosage of 0.5µg per kg body weight and OAA/ SSCALE is 5 (alert). So for the very short duration procedure of cystoscopy which is otherwise show moderate to severe pain can be reduced by dexmedetomidine dosage of 0.5µg/kg without any sedation. Thus this dosage is safe for cystoscopy. Dexmedetomidine loading dose with no infusion provides safe, effective adjunct analgesia, without undesirable hemodynamic effects in cystoscopy. In conclusion at a dose of 0.5 µg/kg of inj. Dexmedetomidine the pain score is mild to moderate as compared to moderate to severe pain experienced in cystoscopy. At this dosage the anxiolytic and sedative properties of the drug were not evident.

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Conflict of Interest: Nil

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