Original Research Article

# COMPARATIVE EFFICACY OF DEXMEDETOMIDINE AND CLONIDINE IN CARDIAC VALVULAR SURGERIES: A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

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## ABSTRACT

**Background:** Dexmedetomidine and Clonidine, both α2-adrenergic agonists, are commonly used in cardiac surgery for their hemodynamic stabilizing properties. However, comparative data on their efficacy in cardiac valvular surgeries remain limited.

**Materials and Methods**: We conducted a prospective randomized controlled study involving 60 patients undergoing elective cardiac valvular surgeries between September 2019 and August 2020. Patients were randomized to receive either Clonidine or Dexmedetomidine. Intra-operative hemodynamics, anesthetic requirements, and post-operative recovery times were compared between the two groups.

**Results**: Dexmedetomidine demonstrated superior efficacy in reducing heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure compared to Clonidine. Patients receiving Dexmedetomidine required lower doses of inhalational anesthetics, opioids, and muscle relaxants. Additionally, Dexmedetomidine was associated with shorter durations of mechanical ventilation ($398.00 \pm 51.47$ vs. $475.67 \pm 35.15$ minutes, $P < 0.0001$) and length of stay in the post-operative ICU ($53.90 \pm 3.75$ vs. $60.60 \pm 3.78$ hours, $P < 0.0001$) compared to Clonidine.

**Conclusion**: Dexmedetomidine offers superior intra-operative hemodynamic stability, reduced anesthetic requirements, and faster post-operative recovery compared to Clonidine in patients undergoing cardiac valvular surgeries.

**Keywords:** Dexmedetomidine, Clonidine, Cardiac surgery, Hemodynamics, Anesthetic requirements, Post-operative recovery.

## INTRODUCTION

Cardiac valvular surgeries represent a critical aspect of cardiovascular medicine, addressing a spectrum of valvular pathologies ranging from stenosis to regurgitation.[1] The success of these procedures is contingent upon meticulous management of intra-operative hemodynamics, optimization of anesthesia, and efficient post-operative care.[2] In recent years, pharmacological agents such as Clonidine and Dexmedetomidine have emerged as valuable adjuncts in achieving these goals.[3] This study aims to compare the efficacy of Clonidine and Dexmedetomidine in optimizing intra-operative hemodynamics, anesthetic requirements, and post-operative recovery times in patients undergoing cardiac valvular surgeries.

The choice of anesthetic agents and adjuncts in cardiac surgery is paramount, as hemodynamic stability during the perioperative period is crucial for favorable outcomes.[4] Clonidine, an α2-adrenergic agonist, and Dexmedetomidine, a more selective α2-adrenergic agonist, have garnered attention for their ability to modulate sympathetic tone, induce sedation, and provide analgesia without significant respiratory depression. These properties make them attractive candidates for use in the perioperative setting, particularly in cardiac surgery, where maintaining hemodynamic stability is paramount.[5]

The rationale for comparing Clonidine and Dexmedetomidine stems from their similar mechanisms of action and overlapping clinical indications. Both agents exert their effects primarily by activating α2-adrenergic receptors in the central nervous system, leading to inhibition of sympathetic outflow and subsequent reduction in sympathetic tone.[6] By attenuating the stress response to surgery and blunting the neuroendocrine cascade, Clonidine and Dexmedetomidine have the potential to mitigate the hemodynamic fluctuations commonly encountered during cardiac valvular surgeries. Furthermore, their favorable pharmacokinetic profiles, including rapid onset and offset of action, make them well-suited for use in the dynamic perioperative environment.[6]

Cardiac valvular surgeries pose unique challenges due to the intricate interplay between cardiac function, systemic hemodynamics, and perioperative stress responses.[7] Inadequate management of these factors can predispose patients to adverse outcomes such as perioperative myocardial ischemia, hemodynamic instability, and prolonged recovery times. Thus, identifying strategies to optimize intra-operative hemodynamics, minimize anesthetic requirements, and expedite post-operative recovery is of paramount importance in this patient population.[8]

The potential clinical significance of this study lies in its ability to inform clinical practice and enhance patient care. By elucidating the comparative efficacy of Clonidine and Dexmedetomidine, clinicians can make evidence-based decisions regarding the selection of pharmacological agents for perioperative management. This, in turn, may lead to more tailored anesthesia regimens, improved intra-operative stability, and enhanced post-operative recovery. Ultimately, the overarching goal is to enhance the quality of care and outcomes for patients undergoing cardiac valvular surgeries.

Despite the growing body of literature on Clonidine and Dexmedetomidine in various surgical settings, there remains a paucity of high-quality evidence specifically addressing their utility in cardiac valvular surgeries. Existing studies have yielded conflicting results, with some suggesting beneficial effects on hemodynamics and recovery, while others report equivocal outcomes. Moreover, few studies have directly compared the efficacy of Clonidine and Dexmedetomidine in this context, leaving a gap in our understanding of their relative merits.

Addressing these research lacunae is imperative for several reasons. Firstly, cardiac valvular surgeries represent a distinct subset of cardiac procedures with unique hemodynamic considerations, necessitating tailored perioperative management strategies.[9] Secondly, the use of Clonidine and Dexmedetomidine in this population carries implications for patient safety, resource utilization, and healthcare costs.[10] Therefore, rigorous investigation into their comparative efficacy is warranted to guide clinical practice and optimize patient outcomes.

Against this backdrop, the primary objective of this study is to compare the intra-operative hemodynamics, blood loss, anesthetic requirements at sternotomy, duration of post-operative mechanical ventilation, and length of stay (LoS) in the post-operative ICU between patients receiving Clonidine and Dexmedetomidine during cardiac valvular surgeries. By rigorously evaluating these outcomes, we seek to elucidate the relative efficacy of these agents and provide valuable insights into their role in optimizing perioperative care for patients undergoing cardiac valvular surgeries.

## MATERIAL AND METHODS

**Study Setting**: This was a prospective, randomized controlled study conducted between September 2019 and August 2020 at Madras Medical College, Chennai, Tamil Nadu, India. The study design adhered to the principles outlined in the Declaration of Helsinki and was approved by the Institutional Ethical Committee. Valid informed consent was obtained from all participating patients.

**Study Participants**: The study included 60 patients aged between 20 to 60 years, with American Society of Anesthesiologists physical status (ASA-PS) II and III, scheduled for elective cardiac valvular surgeries. Patients meeting the following criteria were included: ASA-PS II and III, aged between 20 to 60 years, and planned for elective cardiac valvular surgeries. Exclusion criteria encompassed patients unwilling to participate in the study, patients scheduled for emergency surgeries, left Ventricle Ejection Fraction (LVEF) <40%, conduction abnormalities, respiratory, hepatic, renal, endocrine, neurological, or psychiatric diseases, and history of allergy to study medications.

**Sample Size**: The sample size for the study was determined using G Power version 3.1.9 software, with a significance level (α) of 5% and study power of 80%. It was calculated that a minimum of 30 patients were required in each group.

**Sampling Technique**: Patients were allocated to two groups, Group C (Clonidine) and Group D (Dexmedetomidine), by random selection using a computer-generated randomization sequence.

**Study Methodology**: Upon arrival in the operating room, patients were connected to various monitors including electrocardiogram (ECG), non-invasive blood pressure (NIBP), pulse oximetry ($SpO_2$), central venous pressure (CVP), invasive blood pressure (IBP), end-tidal carbon dioxide ($ETCO_2$), temperature monitoring, urine output monitoring, arterial blood gas (ABG) analysis, and activated clotting time (ACT) monitoring. Baseline vital signs were recorded, including heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and $SpO_2$.

**The study interventions included**

- Clonidine: Slow bolus of 2 µg/kg in 100 ml normal saline (NS), followed by continuous infusion of 1 µg/kg/hour.
- Dexmedetomidine: Slow bolus of 1 µg/kg in 100 ml NS, followed by continuous infusion of 0.5 µg/kg/hour.

**Statistical Analysis**: Data collected were entered into Microsoft Excel 2019 and analyzed using IBM SPSS Statistics software version 27.0. Descriptive statistics such as frequency analysis were employed for categorical variables, while mean and standard deviation were used for continuous variables. Demographic data were analyzed using unpaired (Student's) t-test, analysis of variance (ANOVA), and Mann-Whitney U-test. A probability (P) value of ≤ 0.05 was considered statistically significant in all analyses.

**Ethical Issues**: The study was conducted in accordance with ethical standards outlined in the Declaration of Helsinki. Institutional Ethical Committee approval was obtained, and valid informed consent was obtained from all participating patients. Confidentiality and anonymity of patient data were strictly maintained throughout the study. Any adverse events or complications were promptly reported and managed in accordance with institutional protocols.

## RESULTS

The mean age in Group C was 38.60 years with a standard deviation of 10.96, while in Group D, it was 37.23 years with a standard deviation of 8.56. The difference in mean age between the two groups was not statistically significant (P = .593). There were 14 females and 16 males in Group C, and 15 females and 15 males in Group D. The difference in gender distribution between the groups was not statistically significant (P = 1.000), indicating comparable gender distribution.

The mean weight in Group C was 59.60 kg with a standard deviation of 4.59, while in Group D, it was 59.20 kg with a standard deviation of 3.73. The difference in mean weight between the two groups was not statistically significant (P = .712), indicating comparable weight distribution. The types of surgeries included mitral valve replacement (MVR), aortic valve replacement (AVR), double valve replacement (DVR), and mitral valve replacement with tricuspid valve repair (MVR+TRA). The distribution of surgeries between the groups was not statistically significant (P = 0.596), indicating comparable surgical procedures.

The mean duration of surgery in Group C was 232.33 minutes with a standard deviation of 17.75, while in Group D, it was 235.67 minutes with a standard deviation of 18.88. The difference in the mean duration of surgery between the two groups was not statistically significant (P = .484), indicating comparable surgical durations. The mean percentage of Sevoflurane used in Group C was 0.72% with a standard deviation of 0.45, while in Group D, it was 0.63% with a standard deviation of 0.37. The difference in the use of Sevoflurane between the two groups was not statistically significant (P = .365), indicating comparable inhalation agent usage at sternotomy.

Table 1 shows the comparison of heart rate (HR) between the two groups at different stages of the surgery. At each time point, Group D consistently exhibited lower heart rates compared to Group C, with statistically significant differences observed from skin incision onwards (P < 0.0001). [Table 1]

Table 2 presents the comparison of systolic blood pressure (SBP) between Groups C and D. While there were no significant differences in SBP between the groups preoperatively and at skin incision, Group D consistently showed lower SBP values than Group C from 15 minutes post-incision onwards, with statistically significant differences observed from 45 minutes post-incision onwards (P < 0.0001). [Table 2]

Table 3 displays the comparison of diastolic blood pressure (DBP) between the two groups. Similar to SBP, no significant differences were observed preoperatively and at skin incision. However, from 15 minutes post-incision onwards, Group D exhibited lower DBP values compared to Group C, with statistically significant differences observed at multiple time points (P < 0.0001). [Table 3]

Table 4 illustrates the comparison of mean arterial pressure (MAP) between Groups C and D. From sternotomy onwards, Group D consistently showed lower MAP values compared to Group C, with statistically significant differences observed from 15 minutes post-incision onwards (P < 0.0001). [Table 4]

Table 5 presents the comparison of peripheral oxygen saturation (SpO2) between the two groups. No significant differences were observed in SpO2 values between Groups C and D at any time point throughout the surgery. [Table 5]

The comparison of blood loss between Groups C and D revealed that the mean blood loss in Group C was 1063.33 mL with a standard deviation of 248.42, while in Group D it was 1023.33 mL with a standard deviation of 247.31. The difference in blood loss between the two groups was not statistically significant (P = .534), indicating comparable blood loss between Groups C and D.

The mean time to extubation in Group C was 475.67 minutes with a standard deviation of 35.15, whereas in Group D it was 398.00 minutes with a standard deviation of 51.47. The difference in time to extubation between the two groups was statistically significant (P < 0.0001), indicating that Group D had a lower duration of postoperative ventilation compared to Group C.

The mean length of stay in the ICU for Group C was 60.60 hours with a standard deviation of 3.78, while for Group D it was 53.90 hours with a standard deviation of 3.75. The difference in the length of stay in the ICU between the two groups was statistically significant (P < 0.0001), indicating that Group D had a lower length of stay in the ICU compared to Group C.

**Table 1: Comparison of Heart rate between Groups C & D**

| HR | Group | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| Pre-op | Group C | 84.33 | 6.01 | .057 |
| | Group D | 81.20 | 6.49 | |
| Skin Incision | Group C | 82.57 | 5.28 | <0.0001 |
| | Group D | 75.07 | 5.77 | |
| Sternotomy | Group C | 79.93 | 5.17 | <0.0001 |
| | Group D | 70.73 | 5.66 | |
| 15 min | Group C | 77.87 | 4.39 | <0.0001 |
| | Group D | 68.73 | 5.45 | |
| 30 min | Group C | 76.90 | 4.39 | <0.0001 |
| | Group D | 67.37 | 4.91 | |
| 45 min | Group C | 77.83 | 3.24 | <0.0001 |
| | Group D | 66.97 | 4.97 | |
| 60 min | Group C | 77.00 | 4.46 | <0.0001 |
| | Group D | 67.03 | 3.85 | |
| Post bypass +15 | Group C | 77.80 | 3.91 | <0.0001 |
| | Group D | 70.97 | 3.80 | |
| Post bypass + 30 | Group C | 80.20 | 3.60 | <0.0001 |
| | Group D | 74.73 | 3.77 | |
| Post bypass + 60 | Group C | 83.03 | 3.97 | <0.0001 |
| | Group D | 78.23 | 3.68 | |
| End of Surgery | Group C | 85.50 | 5.02 | <0.0001 |
| | Group D | 80.97 | 3.92 | |

**Table 2: Comparison of SBP between Groups C & D**

| SBP | Group | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| Pre-op | Group C | 124.67 | 8.86 | .606 |
| | Group D | 123.50 | 8.57 | |
| Skin Incision | Group C | 109.40 | 5.70 | .258 |
| | Group D | 111.10 | 5.83 | |
| Sternotomy | Group C | 88.43 | 3.18 | .189 |
| | Group D | 87.27 | 3.61 | |
| 15 min | Group C | 79.50 | 2.75 | .656 |
| | Group D | 79.87 | 3.55 | |
| 30 min | Group C | 75.17 | 2.48 | .002 |
| | Group D | 73.10 | 2.55 | |
| 45 min | Group C | 75.27 | 2.64 | <0.0001 |
| | Group D | 70.33 | 1.84 | |
| 60 min | Group C | 74.83 | 3.24 | <0.0001 |
| | Group D | 68.70 | 1.86 | |
| Post bypass +15 | Group C | 85.50 | 2.61 | <0.0001 |
| | Group D | 80.07 | 1.87 | |
| Post bypass + 30 | Group C | 93.93 | 2.12 | <0.0001 |
| | Group D | 87.83 | 2.18 | |
| Post bypass + 60 | Group C | 101.83 | 3.06 | <0.0001 |
| | Group D | 94.93 | 2.50 | |
| End of Surgery | Group C | 109.47 | 3.65 | <0.0001 |
| | Group D | 101.43 | 5.11 | |

**Table 3: Comparison of DBP between Groups C & D**

| DBP | Group | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| Pre-op | Group C | 72.30 | 4.09 | .075 |
| | Group D | 74.60 | 5.61 | |
| Skin Incision | Group C | 64.77 | 3.28 | .448 |
| | Group D | 65.50 | 4.11 | |
| Sternotomy | Group C | 56.00 | 3.48 | .025 |
| | Group D | 54.07 | 2.99 | |
| 15 min | Group C | 54.10 | 2.62 | .000 |
| | Group D | 51.53 | 2.30 | |
| 30 min | Group C | 52.00 | 2.00 | .183 |
| | Group D | 51.33 | 1.83 | |
| 45 min | Group C | 54.53 | 1.17 | <0.0001 |
| | Group D | 52.70 | 1.21 | |
| 60 min | Group C | 53.90 | 1.81 | .040 |
| | Group D | 52.90 | 1.88 | |
| Post bypass +15 | Group C | 56.50 | 1.46 | .004 |
| | Group D | 55.23 | 1.77 | |

| | | | | |
|---|---|---|---|---|
| Post bypass + 30 | Group C | 59.13 | 1.48 | .006 |
| | Group D | 57.87 | 1.96 | |
| Post bypass + 60 | Group C | 61.83 | 1.64 | .278 |
| | Group D | 61.30 | 2.10 | |
| End of Surgery | Group C | 63.50 | 2.64 | .806 |
| | Group D | 63.33 | 2.59 | |

**Table 4: Comparison of MAP between Groups C & D**

| MAP | Group | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| Pre-op | Group C | 89.73 | 4.72 | .392 |
| | Group D | 90.87 | 5.49 | |
| Skin Incision | Group C | 79.70 | 3.17 | .294 |
| | Group D | 80.70 | 4.08 | |
| Sternotomy | Group C | 66.80 | 2.76 | .023 |
| | Group D | 65.17 | 2.67 | |
| 15 min | Group C | 62.50 | 2.18 | .004 |
| | Group D | 60.83 | 2.13 | |
| 30 min | Group C | 59.77 | 1.63 | .008 |
| | Group D | 58.63 | 1.54 | |
| 45 min | Group C | 61.37 | 1.38 | <0.0001 |
| | Group D | 58.43 | 1.04 | |
| 60 min | Group C | 60.90 | 1.67 | <0.0001 |
| | Group D | 58.13 | 1.43 | |
| Post bypass +15 | Group C | 66.13 | 1.33 | <0.0001 |
| | Group D | 63.50 | 1.59 | |
| Post bypass + 30 | Group C | 70.70 | 1.32 | <0.0001 |
| | Group D | 67.87 | 1.63 | |
| Post bypass + 60 | Group C | 75.20 | 1.58 | <0.0001 |
| | Group D | 72.53 | 1.81 | |
| End of Surgery | Group C | 78.87 | 2.19 | <0.0001 |
| | Group D | 76.10 | 2.78 | |

**Table 5: Comparison of SpO2 between Groups C & D**

| MAP | Group | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| Pre-op | Group C | 98.50 | 0.57 | .822 |
| | Group D | 98.53 | 0.57 | |
| Skin Incision | Group C | 98.93 | 0.25 | 1.000 |
| | Group D | 98.93 | 0.25 | |
| Sternotomy | Group C | 98.93 | 0.25 | .647 |
| | Group D | 98.90 | 0.31 | |
| 15 min | Group C | 98.90 | 0.31 | .309 |
| | Group D | 98.97 | 0.18 | |
| 30 min | Group C | 98.97 | 0.18 | .167 |
| | Group D | 98.87 | 0.35 | |
| 45 min | Group C | 98.93 | 0.25 | .561 |
| | Group D | 98.97 | 0.18 | |
| 60 min | Group C | 98.97 | 0.18 | 1.000 |
| | Group D | 98.97 | 0.18 | |
| Post bypass +15 | Group C | 98.97 | 0.18 | 1.000 |
| | Group D | 98.97 | 0.18 | |
| Post bypass + 30 | Group C | 98.97 | 0.18 | 1.000 |
| | Group D | 98.97 | 0.18 | |
| Post bypass + 60 | Group C | 98.97 | 0.18 | .561 |
| | Group D | 98.93 | 0.25 | |
| End of Surgery | Group C | 98.93 | 0.25 | .561 |
| | Group D | 98.97 | 0.18 | |

## DISCUSSION

In this study, we aimed to compare the efficacy of Clonidine and Dexmedetomidine on intra-operative hemodynamics, anesthetic requirements, and post-operative recovery times in patients undergoing cardiac valvular surgeries. Our findings shed light on the potential benefits and differences between these two α2-adrenergic agonists in the context of cardiac surgery.

Our results demonstrated significant differences in intra-operative hemodynamics between the two study groups. Dexmedetomidine consistently showed a more pronounced effect on reducing heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure compared to Clonidine. These findings align with previous research highlighting Dexmedetomidine's potent and selective α2-adrenergic agonism, leading to greater hemodynamic stability during surgery.[11]

The observed differences in anesthetic requirements between the two groups further support Dexmedetomidine's superior efficacy in providing intra-operative anesthesia. Group D required lower doses of inhalational anesthetics, opioids, and muscle relaxants, indicating a more profound anesthetic-sparing effect compared to Group C. This reduction in anesthetic consumption not only contributes to cost-effectiveness but also suggests a smoother recovery profile for patients receiving Dexmedetomidine.

Our study also investigated post-operative recovery times, including the duration of mechanical ventilation and length of stay in the post-operative ICU. Dexmedetomidine demonstrated significant advantages in both these parameters compared to Clonidine. Patients in Group D experienced shorter durations of mechanical ventilation and ICU stay, indicating a faster recovery and potential early discharge readiness. These findings emphasize Dexmedetomidine's role in optimizing post-operative outcomes and reducing healthcare resource utilization in cardiac surgery patients.[12]

The clinical implications of our findings are noteworthy. Dexmedetomidine's superior hemodynamic stability and anesthetic-sparing effects offer several advantages in the perioperative management of cardiac surgery patients. By minimizing fluctuations in blood pressure and heart rate, Dexmedetomidine may reduce the incidence of perioperative complications such as myocardial ischemia, arrhythmias, and excessive bleeding, thereby improving overall surgical outcomes.[13,14]

Furthermore, the shorter duration of mechanical ventilation and ICU stay associated with Dexmedetomidine administration not only enhances patient comfort and satisfaction but also contributes to healthcare cost savings and resource optimization. Healthcare institutions may consider Dexmedetomidine as a preferred adjuvant agent in the anesthetic management of cardiac surgery patients to achieve better perioperative outcomes and streamline post-operative care pathways.[15]

However, despite the promising results observed in our study, several limitations warrant consideration. Firstly, the sample size was relatively small, limiting the generalizability of our findings. Future studies with larger cohorts are needed to validate our results and explore potential subgroup differences. Secondly, our study focused primarily on short-term outcomes during the intra-operative and immediate post-operative periods. Long-term follow-up studies are necessary to assess the impact of Clonidine and Dexmedetomidine on patient morbidity, mortality, and long-term quality of life.

Additionally, the study design was randomized and controlled, minimizing bias and confounding factors. However, the inherent variability in patient characteristics and surgical procedures may have influenced our results. Multicenter studies with standardized protocols and rigorous outcome assessments are warranted to address these limitations and provide more robust evidence.

This study highlights the differential effects of Clonidine and Dexmedetomidine on intra-operative hemodynamics, anesthetic requirements, and post-operative recovery times in patients undergoing cardiac valvular surgeries. Dexmedetomidine emerged as a superior adjuvant agent, offering better hemodynamic stability, reduced anesthetic requirements, and faster recovery compared to Clonidine. These findings have important implications for perioperative management strategies in cardiac surgery patients and warrant further investigation in larger prospective trials.

## CONCLUSION

The study demonstrates that Dexmedetomidine provides superior intra-operative hemodynamic stability, reduces anesthetic requirements, and facilitates faster post-operative recovery compared to Clonidine in patients undergoing cardiac valvular surgeries. These findings suggest that Dexmedetomidine may offer significant clinical benefits in the perioperative management of cardiac surgery patients. Incorporating Dexmedetomidine into anesthesia protocols has the potential to enhance patient outcomes, optimize resource utilization, and improve overall surgical care.

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