ISSN 2091-2889 (Online)
ISSN 2091-2412 (Print)

Journal of Chitwan Medical College 2018;8(25):15-18
Available online at: www.jcmc.cmc.edu.np

ORIGINAL RESEARCH ARTICLE

CONSCIOUS SEDATION FOR BALLOON MITRAL VALVULOPLASTY

Bharati Devi Sharma[1], Gopendra Prasad Deo[1], Indra Narayan Shrestha[1], Shyam Raj Regmi[2]
[1]Department of Anesthesiology & Critical Care, Chitwan Medical College, Bharatpur, Chitwan, Nepal
[2]Department of Cardiology, Chitwan Medical College, Bharatpur, Chitwan, Nepal
***Correspondence to:** Dr. Bharati Devi Sharma, Department of Anesthesiology & Critical Care, Chitwan Medical College, Bharatpur, Chitwan, Nepal.*
Email: bharututh@hotmail.com

ABSTRACT

Introduction: Analgesia and sedation are required for the comfort of patient and the cardiologist during Balloon mitral valvotomy. Efficacy of analgesia, sedation, and patient satisfaction with conscious sedation and local anesthesia was compared with local anaesthesia only during procedure. **Methods**: This was single-centered, prospective study conducted in Chitwan Medical College. All 66 patients, who underwent Balloon mitral valvotomy from February 2015 to January 2017, were enrolled in this study. They were divided into two groups by computer generated randomization. Thirty three patients received bolus injection fentanyl 1 mcg/kg and injection midazolam bolus 0.02 mg/kg along with local anaesthesia (20ml xylocaine) at femoral puncture site and other 33 patients received local anaesthesia only. Pain intensity (by visual analog score), anxiety score, overall patient and operator's satisfaction, and effect on cardio respiratory parameters were assessed. Student's unpaired t-test was applied. $P < 0.05$ was considered statistically significant. **Results**: Both the groups were comparable with respect to age, gender and pre and post balloon mitral valvotomy mitral valve area. Statistically significant difference was found with respect to anxiety score (1.1 + 0.43 Vs. 1.99 + 0.01), VAS score (operator's opinion) (9.10 + 0.56 Vs. 7.53 + 1.01) and VAS score (patient's opinion) (8.54 + 0.87 Vs. 5.55 + 1.14). Fall in systolic pressure, diastolic blood pressure, mean arterial blood pressure, and respiratory rate was found in fentanyl group, but the values were within normal limits and statistically not significant. **Conclusion**: Conscious sedation with bolus dose of fentanyl and midazolam with local anesthesia at puncture site is better than only local anesthesia during balloon mitral valvotomy procedure to relieve patient's anxiety and to improve patient's and operator's comfort without affecting hemodynamic parameters.

Key words: Balloon mitral valvotomy, Conscious sedation, Fentanyl

INTRODUCTION

Balloon mitral valvotomy (BMV) constitutes an important alternative to surgical closed mitral valvotomy for the treatment of rheumatic mitral stenosis and is usually done under local anesthesia with moderate sedation under monitored anesthesia care.[1,2]

Conscious sedation is a minimally depressed level of consciousness that retains the patient's ability to maintain his or her airway independently and continuously and to respond appropriately to physical stimulation and verbal commands.[3] No intervention is required to maintain a patent airway and cardiovascular stability.[4] Joint Commission on Accreditation of Healthcare Organization in 2001 has coined the term "moderate sedation" for conscious sedation.[4] Conscious sedation helps to expedite the conduct of procedures that are particularly not uncomfortable but that require that the patient does not move.[3]

We chose cardio stable potent narcotic analgesic agent fentanyl and Midazolam was chosen to produce complete amnesia and due to its faster onset of action and short recovery time.[5,6] This study compares fentanyl and midazolam combination with local anaesthesia without conscious sedation in patients undergoing balloon mitral valvotomy. Pain intensity (by visual analog score [VAS]), anxiety score, overall patient and operator's satisfaction,

and effect on cardio respiratory parameters were assessed.

METHODS

This prospective study was carried out in Chitwan Medical College from February 2015 to January 2017. Sixty six patients with rheumatic mitral stenosis with valve area of <1.0 cm^2 in the age group of 15–45 years, of both genders, scheduled for elective balloon mitral valvotomy were included in the study. Patients with Wilkin's score >10, pregnant and lactating mothers, patients with anticipated difficult airway, patients with a history of bronchial asthma, chronic obstructive pulmonary disease, liver disease, and renal disease, patients with a history of allergies to drugs, and patients with congestive cardiac failure and hemodynamic instability were excluded from the study. Complete preanesthetic examination was done before the procedure. In pre-procedural assessment patient's vital signs such as heart rate, blood pressure, arterial oxygen saturation, and respiratory rate were noted. Cardiovascular and respiratory systems were thoroughly examined, and routine and specific investigations were noted. Preprocedural starvation of 6 hours was confirmed. Patients didn't receive preoperative medication before coming to catheterization laboratory. Patients were informed to communicate about any discomfort during the procedure. Baseline anxiety score was noted on arrival to the laboratory. This was graded as "0" for none or minimal signs of anxiety such as agitation, sweating, tearing, or verbal expression by the patient. A score of "1" for moderate and "2" for severe anxiety. They were positioned on table and an infusion with intravenous fluid was started. Monitoring included pulse oximeter, ECG, respiratory rate, and oxygen at 6 L/min was supplemented via Hudson's mask.

They were divided into two groups by computer generated randomization. Group 1 patients received intravenous fentanyl 1 µg/kg and midazolam 0.02 mg/kg as a loading dose. Group 2 patients received no sedation.

The area was prepared, draped, and infiltrated with long-acting local anesthetic agent (lignocaine) by the cardiologist. Femoral puncture was done. Cardiovascular parameters (heart rate and blood pressure) and respiratory parameters (oxygen saturation and respiratory rate) were monitored throughout the procedure.

At conclusion of the procedure, the cardiologist was asked to give a visual analog score (VAS) on a scale from 0 to 10, where 0 will be referred to cases where the procedure had to be abandoned or general anesthesia induced due to inappropriate sedation and 10 referred to cases where the patient was fully cooperative in all respects.After arrival in the recovery room, the patient was also asked to state a VAS for overall satisfaction with the anesthetic management. The patients' satisfaction was assessed by asking the patient about recall of their comfort level, of painful or unpleasant events during the procedure. They were then asked to grade VAS from 0 to 10, 0 being as the worst experience, they have ever had and 10 being a good experience and they would undergo it again if needed. The results were analyzed using SPSS software. Student's paired and unpaired t-test were applied. Data were expressed as mean ± standard deviation, $P < 0.05$ was considered statistically significant.

RESULTS

All sixty six patients who were enrolled in the study completed the study and were included in data analysis. Demographic data were comparable in both the groups; the mean age being 36.0 ± 11.0 7 in fentanyl group and 35 ± 10.11 in local anaesthesia only group. Both the groups were comparable with respect to gender and pre and post balloon mitral valvotomy mitral valve area.[Table 1] Statistically significant difference was found with respect to anxiety score (1.1 + 0.43 Vs. 1.99 + 0.01), VAS score (operator's opinion) (9.10 + 0.56 Vs. 7.53 + 1.01) and VAS score (patient's opinion) (8.54 + 0.87 Vs. 5.55 + 1.14). [Table 2]

Mean heart rates were comparable in both the groups. Fall in systolic pressure, diastolic blood pressure, mean arterial blood pressure, and respiratory rate was found in fentanyl group, but the values were within normal limits and statistically not significant.

Table 1: Clinical characteristics

	Group 1 (Fentanyl, midazolam and LA)	Group 2 (LA)
Mean age	36 + 11.07	35 + 10.11
Male	10(30.31%)	13(39.39%)
Female	23 (69.69%)	20 (60.61%)
Pre BMV MVA	0.8 + 0.12 cm^2	0.85 + 0.11 cm^2
Post BMV MVA	1.7 + 0.28 cm^2	1.75 + 0.21 cm^2

Table 2: Comparison of scores and other variables

	Group 1 (Fentanyl, midazolam and LA)	Group 2 (LA)	P value
VAS score operator opinion	9.10 + 0.56	7.53 + 1.01	< 0.05
VAS score patient opinion	8.54 + 0.87	5.55 + 1.14	<0.05
Anxiety score	1.1 + 0.43	1.99 + 0.01	<0.05
Heart Rate	78 + 21	82 + 24	>0.05
Respiratory rate	21 + 3.6	24 + 4.5	>0.05
Systolic BP	98 + 11.4	101 + 12.3	>0.05
Diastolic BP	70 + 6.5	75 + 8.3	>0.05
Mean BP	75.5 + 5.4	78.3 + 6.2	>0.05
SPo2	99%	98%	>0.05

DISCUSSION:

Many patients require sedation during diagnostic or therapeutic procedures. Ideally, procedural sedation minimizes the patient's awareness and discomfort while maintaining the patient's safety.[7]

Balloon mitral valvotomy is a minimally invasive procedure and does not require general anesthesia. Most of the time, it is performed under local anaesthesia in cathlab.[8] Procedure generally is not painful, but discomfort and pain can occur during insertion of catheters and dilatation of tract, septal puncture, and balloon dilatation. Patient will experience discomfort from lying still on an uncomfortable table. Patient immobility is extremely important, especially during transseptal puncture and balloon dilatation. Hence, sedation with drugs which will alleviate patient's anxiety, fear associated with the procedure and at the same time will maintain patient's hemodynamic condition is required. Conscious sedation provides analgesia, anxiolysis, amnesia, and sedation so as to make the procedure comfortable.[9]

The combination of fentanyl and midazolam has been used for many years. These medications have a rapid onset and a short duration of action, and are safe and effective for PSAA.

Midazolam is a benzodiazepine that can be delivered by a number of different routes, but intravenous administration provides the fastest onset of action. Midazolam undergoes hepatic metabolism and renal excretion, and prolonged effects may be seen with dysfunction of either organ system Midazolam is a sedative, amnestic, and anxiolytic medication with no analgesic properties. For this reason, it is used commonly with an opioid analgesic such as fentanyl.[10]

Fentanyl is a synthetic opioid. When given intravenously, the time of onset is one to two minutes and the duration of clinical effect is about 30 to 60 minutes. Fentanyl is metabolized by the liver, but its short duration of effect is attributable to rapid redistribution from the central nervous system. Because fentanyl is a pure analgesic, it should not be

used alone for PSAA.[11]

Fentanyl and midazolam are titrated easily and are widely available. The biggest drawback of this combination is the potential for cardiac and respiratory depression. The medications should be given in slow, incremental doses rather than using bolus administration. Respiratory depression may occur in 25 percent or more of patients.[12,13]

In our study, we use bolus doses. Intermittent another bolus dose administration is required in very few patients. Significant cardiorespiratory depression was not found. Conscious sedation was found better in terms of relieving anxiety and operators and patient comfort without significant hemodynamic compromise.

CONCLUSION:

Conscious sedation with bolus dose of fentanyl and midazolam with local anaesthesia at puncture site is better than only local anaesthesia during balloon mitral valvotomy procedure to relieve patient's anxiety and to improve patient's and operator's comfort without affecting hemodynamic parameters. Both the drugs fentanyl and midazolam are suitable for conscious sedation for balloon mitral valvotomy with respect to sedation, amnesia and effects on cardiorespiratory drugs.

REFERENCES:

1. Tucker PA, Ferguson JJ, Harlan M, Gaos CM, Massumi A. Balloon mitral valvuloplasty: Clinical experience at the Texas Heart Institute. Tex Heart Inst J. 1992;19:270–7.

2. Regmi SR, Dhital BM, Sharma B et al. Balloon mitral valvuloplasty (BMV): An early experience in Chitwan Medical College. JCMC. 2015;5(14):6-9.

3. American Society of Anaesthesiologist task force on sedation and analgesia by non anaesthesiologists. Practice guidelines for sedation and analgesia by non anaesthesiologist. Anesthesiology. 2002;96:1004–17.

4. Bahn EL, Holt KR. Procedural sedation and analgesia: A review and new concepts. Emerg Med Clin North Am. 2005;23:503–17.

5. Bailey PL, Streisand JB, East KA, East TD, Isern S, Hansen TW, et al. Differences in magnitude and duration of opioid-induced respiratory depression and analgesia with fentanyl and sufentanil. Anesth Analg. 1990;70:8–15.

6. Glass PS, Shaffer SL, Raves JG. Miller's Anaesthesia. 7th ed. Philadelphia: Churchill Livingstone Elsevier; 2007. Intravenous drug delivery system; pp. 719–68.

7. Todd BB, Luis ML, Dinora P, Am Fam Physician. 2005 Jan 1;71(1):85-90.

8. Regmi SR, Maskey A, Dubey L et al. Balloon mitral valvuloplasty (BMV) in pregnancy: a four year experience at shahid Gangalal National Heart center (SGNGC), Nepal. NHJ 2009;6:35-38.

9. Modak SD, Kane DG. Conscious Sedation for Balloon Mitral Valvotomy: A Comparison of Fentanyl versus Sufentanil. Ann Card anaesth. 2017;20(2):163-168.

10. Midazolam. USP Dispensing Information. Englewood, Colo. Micromedex. 2001;1:2074–81.

11. Fentanyl derivatives. USP Dispensing Information. Englewood, Colo. Micromedex. 2001;1:1495–503.

12. Kennedy RM, Porter FL, Miller JP, Jaffe DM. Comparison of fentanyl/midazolam with ketamine/midazolam for pediatric orthopedic emergencies. Pediatrics. 1998;102(4 pt 1):956–63.

13. Bailey PL, Pace NL, Ashburn MA, Moll JW, East KA, Stanley TH. Frequent hypoxemia and apnea after sedation with midazolam and fentanyl. Anesthesiology. 1990;73:826–30.