# Conscious Sedation for Balloon Mitral Valvotomy: A Comparison of Fentanyl versus Sufentanil


## Abstract

**Context:** Analgesia and sedation are required for the comfort of patient and the cardiologist during balloon mitral valvotomy. **Aims:** In this study, efficacy of analgesia, sedation, and patient satisfaction with sufentanil was compared with fentanyl. **Settings and Design:** Single-centered, prospective single-blind study of sixty patients. **Materials and Methods:** Patients between 15 and 45 years of rheumatic mitral stenosis with valve area of 0.8–1 $cm^2$ undergoing elective balloon mitral valvotomy, randomly divided to receive bolus injection fentanyl 1 mcg/kg (Group 1, $n = 30$) followed by infusion at 1 mcg/kg/h or bolus of injection sufentanil 0.1 mcg/kg (Group 2, $n = 30$) followed by continuous infusion at 0.1 mcg/h. Both the groups received injection midazolam bolus 0.02 mg/kg followed by infusion at 15 mcg/kg/h. Pain intensity (by visual analog score [VAS]), level of sedation (by Ramsay sedation scale), overall patient and operator's satisfaction, effect on cardiorespiratory parameters, and discharge score (by modified Aldrete score) were assessed. **Statistical Analysis Used:** Statistical analysis used Student's unpaired *t*-test and Chi-square test. $P < 0.05$ was considered statistically significant. **Results:** Mean number of bolus doses in fentanyl group was 0.9 versus 0.13 in sufentanil group ($P < 0.01$). The mean value of mean blood pressure in fentanyl group was 83.52 mmHg versus 88 mmHg in sufentanil group ($P < 0.05$), but the value was within normal range in both the groups. The mean VAS – patient's opinion in fentanyl group was 8.97 versus 9.53 in sufentanil group ($P < 0.05$). Mean discharge score in fentanyl group was 17.87 versus 18.23 in sufentanil group ($P < 0.05$). No statistically significant difference was found with respect to heart rate, respiratory rate, oxygen saturation, $PaCO_2$ values, and anxiety scores. **Conclusion:** Sufentanil was found to be better with respect to analgesia, patient satisfaction, and recovery however not cost-effective for continuous infusion technique.


**Keywords:** *Balloon mitral valvotomy, conscious sedation, fentanyl, sufentanil*


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## Introduction

Balloon mitral valvotomy 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[1,2] under monitored anesthesia care.

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]

Many agents have been used for this purpose. A short-acting benzodiazepine either alone or in combination with opioid is commonly used for procedural sedation.[5]

We chose cardiostable potent narcotic analgesic agents fentanyl and sufentanil in the potency ratio of 1:10.[6]

Midazolam was chosen to produce complete amnesia and due to its faster onset of action and short recovery time.[7]

This randomized single-blind study compares sufentanil and midazolam combination with fentanyl and midazolam combination in patients undergoing



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balloon mitral valvotomy under local anesthesia with the primary end point being level of analgesia, sedation, and patient's satisfaction. Discharge fitness and effect on cardiorespiratory parameters are the secondary end points.

## Materials and Methods

This prospective randomized double single trial was carried out after obtaining approval from the Institutional Ethics Committee. Patients included in this study were informed about the procedure in their own language, and a written informed consent was taken from all of them.

Sixty American Society of Anaesthesiologist-3 patients with rheumatic mitral stenosis with valve area of 0.8–1.0 $cm^2$ 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.

A complete preanesthetic examination was done before the procedure.

In preprocedural 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. Hemoglobin total white blood cell count, erythrocyte sedimentation rate, urine routine, X-ray chest P-A view, echocardiography (ECG), and two-dimensional ECG reports were noted.

In patients above 35 years of age, additional fasting blood sugar, blood urea nitrogen, and serum creatinine were advised.

Preprocedural starvation of 6 hours was confirmed.

Patients received no 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 $PaCO_2$ values and oxygen at 6 L/min was supplemented via Hudson's mask. Arterial blood sample was sent before administration of sedation for $PaCO_2$ value.

Group 1 patients received intravenous fentanyl 1 µg/kg and midazolam 0.02 mg/kg as a loading dose followed by infusion of injection fentanyl 1 µg/kg/h and injection midazolam 15 µg/kg/h. Group 2 patients received injection sufentanil 0.1 µg/kg and injection midazolam 0.02 mg/kg as a loading dose followed by infusion of injection sufentanil 0.1 µg/kg/h and injection midazolam 15 µg/kg/h.

The area was prepared and draped, and the area was infiltrated with long-acting local anesthetic agent (bupivacaine) by the cardiologist. Femoral puncture was done 10 min after starting the infusion. Infusion rates were adjusted by increasing or decreasing the rate to maintain an objective sedation score of 2–3 according to Ramsay sedation scale. If the level of sedation progressed to a score of more than 4 infusion was tapered till the patient's level of sedation came back to 3. Bolus dose of 1 ml was given if the patient complained pain or discomfort.

Cardiovascular parameters (heart rate and blood pressure) and respiratory parameters (oxygen saturation and respiratory rate) and sedation score were monitored throughout the procedure. Arterial blood sample was sent for $PaCO_2$ value during the procedure.

All complications or undesirable events requiring interventions were watched for. Respiratory variables such as oxygen desaturation ($SpO_2$ <90%), hypercarbia ($PaCO_2$ >45 mmHg), respiratory rate (<8/min), airway obstruction, and snoring were watched for. Other events looked for were excessive pain or distress, restlessness or inappropriate movements, excessive sedation, and loss of consciousness by the patient. Furthermore, noted were any "reruns" that were required due to patients' inability to lie still during the procedure, especially during transseptal puncture and balloon dilatation. The other major complications noted were the cessation of procedure or the need for induction of general anesthesia. All technical- and procedure-related complications were documented.

The infusion was stopped at the end of the procedure, and arterial blood sample was again sent for $PaCO_2$ value.

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. One hour after arrival in the recovery room or Cardiac Intensive Care Unit (ICU), 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.

Patient's discharge score was assessed at the end of 2 h using modified Aldrete scoring system.

### Statistical analysis

The mean percentage of patient experiencing pain in fentanyl group 12 (4) reported in the previous study.[8] We considered 32% decrease in the incidence of pain in sufentanil group to be clinically superior.

With power of study 80% and type 1 error of 5%, sample size was calculated as 20 in each group and to compensate for the dropouts, a sample size of 30 participants per group was chosen.

Computer-generated randomization method was used to divide the patients into two groups ($n$ = 60).

The results were analyzed using Student's paired and unpaired $t$-test and Chi-square test. Data were expressed as mean ± standard deviation, $P < 0.05$ was considered statistically significant.

## Observations and Results

All sixty patients who were enrolled in the study completed the study protocol and included in data analysis. Demographic data were comparable in both the groups; the mean age being 25.50 ± 7.51 in fentanyl group and 28.03 ± 6.48 in sufentanil group. Both the groups were comparable with respect to gender [Table 1].

**Table 1: Group-wise comparison of demographic variables**

| | Group | | Total |
|---|---|---|---|
| | Fentanyl | Sufentanil | |
| Female, *n* (%) | 15 (50.00) | 15 (50.00) | 30 (50.00) |
| Male, *n* (%) | 15 (50.00) | 15 (50.00) | 30 (50.00) |
| Total, *n* (%) | 30 (100.00) | 30 (100.00) | 60 (100.00) |
| Age in years | 25.50±7.51 | 28.03±6.48 | *P*-0.167 |

The mean number of bolus doses in fentanyl group was significantly higher (0.9) than sufentanil group (0.13). The difference was significant ($P$ = 0.00019) [Table 2]. VAS score (patient's opinion) was significantly higher in sufentanil group compared to fentanyl group [Table 3].

Discharge score in sufentanil group is significantly higher (18.23) compared to fentanyl group (17.27) with $P$ = 0.027 [Table 3].

No statistically significant difference was found with respect to sedation score, anxiety score, and VAS score (operator's opinion) [Table 3].

Mean heart rates were comparable in both the groups. Significant fall in systolic blood pressure and mean arterial blood pressure was found in fentanyl group compared to sufentanil group, but the values were within normal limits [Table 4].

No significant difference was found with respect to respiratory rate, oxygen saturation, and $PaCO_2$ values in both the groups [Table 4].

There was no significant difference between VAS score of operator and VAS score of patients in both the groups [Table 5].

## Discussion

Balloon mitral valvotomy is a minimally invasive procedure and does not require general anesthesia. Furthermore, the patient's cardiological condition makes it a high-risk procedure if general anesthesia is to be given. Procedure generally is not painful, but discomfort and pain can occur during insertion of catheters and dilatation of tract, septal puncture, and balloon dilatation. Furthermore, the patient will experience discomfort from lying still on

**Table 2: Group-wise comparison of various baseline variables**

| Variables | Group | | | | Unpaired *t*-test applied | | |
|---|---|---|---|---|---|---|---|
| | Fentanyl | | Sufentanil | | | | |
| | Mean | SD | Mean | SD | *t* | *P* | Difference is |
| Onset of procedure postinfusion (min) | 9.13 | 2.21 | 9.50 | 1.66 | −0.728 | 0.470 | Not significant |
| Bolus doses | 0.90 | 1.00 | 0.13 | 0.35 | 3.987 | 0.00019 | Significant |

SD: Standard deviation

**Table 3: Group-wise comparison of various scores**

| Variables | Group | | | | Unpaired *t*-test applied | | |
|---|---|---|---|---|---|---|---|
| | Fentanyl | | Sufentanil | | *t* | *P* | Difference is |
| | Mean | SD | Mean | SD | | | |
| Anxiety score | 1.13 | 0.43 | 1.10 | 0.66 | 0.231 | 0.818 | Not significant |
| VAS score-operator's opinion | 9.07 | 1.02 | 9.37 | 0.81 | −1.266 | 0.210 | Not significant |
| VAS score-patient's opinion | 8.97 | 1.07 | 9.53 | 0.78 | −2.354 | 0.022 | Significant |
| Discharge score | 17.87 | 0.51 | 18.23 | 0.73 | −2.263 | 0.027 | Significant |
| Sedation scale | 2.90 | 0.31 | 2.83 | 0.46 | 0.660 | 0.512 | Not significant |

SD: Standard deviation, VAS: Visual analog score

**Table 4: Group-wise comparison of various hemodynamic variables**

| Variables | Group | | | | Unpaired *t*-test applied | | |
|---|---|---|---|---|---|---|---|
| | Fentanyl | | Sufentanil | | | | |
| | Mean | SD | Mean | SD | *t* | *P* | Difference is |
| Respiratory rate(/min) | 24.60 | 5.79 | 24.90 | 6.40 | −0.190 | 0.850 | Not significant |
| Heart rate (/min) | 94.37 | 23.25 | 91.13 | 14.13 | 0.651 | 0.518 | Not significant |
| SBP (mmHg) | 109.30 | 9.32 | 117.57 | 10.20 | −3.278 | 0.002 | Significant |
| DBP (mmHg) | 70.63 | 6.50 | 73.60 | 10.20 | −1.343 | 0.184 | Not significant |
| Mean arterial pressure | 83.52 | 6.42 | 88.26 | 8.44 | −2.445 | 0.010 | Significant |
| $SpO_2$ (%) | 100.00 | 0.00 | 99.90 | 0.40 | 1.361 | 0.179 | Not significant |
| $PaCO_2$ (mmHg) | 34.69 | 3.94 | 38.46 | 2.86 | −4.248 | 0.0767 | Not Significant |

SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

**Table 5: Comparison between VAS score operator's opinion and patient's opinion in fentanyl and sufentanil group**

| Group | VAS score | Mean | SD | *t* | *P* |
|---|---|---|---|---|---|
| Fentanyl | Operator's opinion | 9.07 | 1.02 | 1.361 | 0.184 |
| | Patient's opinion | 8.97 | 1.07 | Difference is not significant | |
| Sufentanil | Operator's opinion | 9.37 | 0.81 | −1.153 | 0.258 |
| | Patient's opinion | 9.53 | 0.78 | Difference is not significant | |

SD: Standard deviation, VAS: Visual analog score

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.

Fentanyl and sufentanil are short-acting narcotic analgesics. They have a short context-sensitive half-life which is defined as the time required for 50% decrease in drug concentration after stopping infusion. Hence, these drugs can be given by continuous infusion technique. We have chosen to give drugs by continuous infusion as it reduces the total amount of drug used, provides better control over hemodynamic parameters, and ensures rapid recovery.[7]

In our study, sufentanil was found to be a better analgesic compared to fentanyl as evidenced by the number of bolus doses required, VAS score of patients' opinion, and incidence of pain or pain-related movements during the procedure. Phitayakorn *et al*.[9] compared continuous infusions of fentanyl and sufentanil for outpatient anesthesia and found that intraoperatively administered sufentanil proved to be a better postoperative analgesic than intraoperatively administered fentanyl. Fewer patients in the sufentanil group complained of pain.

Bailey *et al*.[6] studied the analgesia with fentanyl and sufentanil and found significant elevation of pain threshold in sufentanil group. Pain threshold returned to control values 180 min after sufentanil but only 90 min after fentanyl.

The degree of sedation was assessed using Ramsay sedation scale. The quality and control of sedation were found to be similar in both the groups.

Phitayakorn *et al*.[9] compared continuous sufentanil and fentanyl infusions for outpatient anesthesia (D and C) and found that level of consciousness (sedation) was more or less similar in both the groups.

Kalenda and Scheijgrond[10] did a comparative study of anesthesia with sufentanil and fentanyl analgesia in undergoing carotid and vertebral angiography and found that patients in sufentanil group were more rapidly awake, lucid than after fentanyl analgesia.

Kugler *et al*.[11] studied the hypnotic effect of fentanyl and sufentanil. They found that rapid eye movements during wakefulness and slow eye movements during sleepiness showed no reliable differences between fentanyl and sufentanil.

Joshi *et al*.[12] compared the analgesic efficacy of fentanyl and sufentanil for chest tube removal after cardiac surgery and found that the sedation scores remained low in both groups, and patients remained alert.

The major goal of outpatient anesthesia should be to allow the patient to leave the hospital as quickly as possible. This involves not only a return to near normal preoperative mental and motor functioning but also minimization of uncomfortable side effects such as pain.[9] This necessitates use the of an anesthetic that will have a short duration of action which will ensure early discharge of the patient. This was done using postanesthesia discharge scoring system developed by Aldrete.[13] The discharge score was tested 2 h after the procedure.

In our study, we found that sufentanil had a statistically significant percentage of patients with a higher discharge score than fentanyl. However, even in fentanyl group, discharge score was never <16 which means that quick recovery is possible even in patients who are given fentanyl.

Phitayakorn *et al*.[9] have compared the continuous infusions of fentanyl and sufentanil for outpatient anesthesia. They found significant differences between time to awakening (appropriate response to verbal commands), time to ambulation, and time to discharge home. Time in the main hospital recovery room was shorter in sufentanil group, but the difference was only 9 min which is probably clinically not significant.

Monk *et al*.[14] studied the pharmacological properties and therapeutic use sufentanil and found that intravenous sufentanil produces anesthesia equivalent to fentanyl and recovery tends to be more rapid after sufentanil.

Ethuin *et al*.[15] studied the pharmacokinetics of long-term sufentanil infusion for sedation in ICU patients and found that rapid distribution and elimination process are responsible for rapid reversibility of sedation with sufentanil maintained after long duration infusion.

In our study, we compared the respiratory effects of two drugs in terms of respiratory rate, partial pressure of carbon dioxide tension in arterial blood ($PaCO_2$), and arterial oxygen saturation. There was no significant fall in respiratory rate and arterial oxygen saturation in both the groups. $PaCO_2$ values in sufentanil group remained higher than the fentanyl group, but it was within normal limits.

Baily *et al*.[6] compared the differences in magnitude and duration of respiratory depression with fentanyl and sufentanil, using end-tidal carbon dioxide and ventilatory and occlusion pressure responses to $CO_2$ rebreathing. Magnitude and duration of respiratory depression occlusion pressure response were significantly less with sufentanil compared to fentanyl. Ventilatory and occlusion pressure responses returned to control values earlier in sufentanil group compared to fentanyl.

Kuglar[11] compared the hypnotic effect of fentanyl and sufentanil and found that sufentanil acts more powerfully on respiratory regulation compared to fentanyl. Periods of apnea occur more frequently with sufentanil but can be interrupted by external psychophysiological stimulation.

Ethuin *et al*.[15] in their study found that sufentanil suitable only for intensive-care patients with a short stay in ICU. Respiratory depression during spontaneous breathing is not significant.

Charlot *et al*.[16] in their study found that respiratory depression required naloxone for two patients with fentanyl.

With respect to heart rate, there was no significant difference in both the groups. However, mean arterial pressure showed a significant fall in fentanyl group compared to sufentanil. This suggests better hemodynamic stability with sufentanil.

Monk *et al*.[14] in their study found that sufentanil maintains hemodynamic stability better than other opioids.

Charlot *et al*.[16] studied pharmacokinetic parameters of fentanyl and sufentanil in supratentorial neurosurgery and found that baseline heart rate and arterial blood pressure were lower and more stable with sufentanil than fentanyl.

Lange *et al*.[17] compared the cardiovascular responses, speed of anesthetic induction with sufentanil-oxygen and fentanyl-oxygen for coronary artery surgery and found a significant increase in blood pressure during incision, sternotomy, or sternal spread in fentanyl group. Hypertension occurred more frequently in fentanyl group, whereas hypertension never occurred in sufentanil group.

In our study, we also monitored for the airway complications during the procedure such as oral airway placement, snoring, or any jaw thrust or mass ventilation required. Chest rigidity due to opioids was also watched for.

To assess the excessive sedative effect of drugs, patient's responsiveness to oral commands; fall in oxygen saturation to <90% was also monitored.

Other complications such as excessive pain or distress, restlessness or inappropriate movements, any resume that was required due to patients required to lie still, and need for induction of general anesthesia were also noted.

None of the patients in both the groups had any airway complications or complications due to excessive sedation.

## Conclusion

In the present study, we found that sufentanil is better than fentanyl with respect to analgesia and recovery from the effects of sedation. Both the drugs fentanyl and sufentanil are suitable for conscious sedation for balloon mitral valvotomy with respect to sedation and effects on cardiorespiratory drugs. However, sufentanil is an expensive drug; it is not cost-effective for continuous infusion technique.

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### Conflicts of interest

There are no conflicts of interest.

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