Original Research Article

Evaluation of the effects of low tidal volume ventilation in patients undergoing urological procedures in lateral position under general anaesthesia – A randomized controlled trial

Alka Lakra[1*], Sona Dave[2]

[1]Speciality Medical Officer, Department of Anaesthesiology, Speciality Medical officer, V N Desai Municipal General, Hospital, Mumbai, Maharashtra, INDIA.
[2]Professor, Department of Anaesthesiology, Topiwala National Medical College & BYL Nair Ch. Hospital, Mumbai, Maharashtra, INDIA.
Email: alkalakra.dr@gmail.com

Abstract

Background: Postoperative pulmonary complications (PPC) following general anaesthesia depends mainly on intraoperative ventilatory strategies. Recent evidences suggest that low tidal volume ventilation may reduce PPC. We compared the postoperative lung functions in patients ventilated with low versus high tidal volumes in lateral decubitus position. **Material and Methods:** After approval from our Institutional Ethical Committee, 30 American Society of Anesthesiologists Physical Status I and II patients were recruited. Patients of either sex in the age group of 18–70 years, undergoing elective open urological surgeries, in lateral position under general anaesthesia were included in this prospective study. Patients were randomized into two groups; L and H. Group L patients were ventilated with 5-7 ml/kg tidal volume, positive end-expiratory pressure (PEEP) of 10 cm H_2O and recruitment manoeuvre (RM) whereas group H patients were ventilated with 10-12 ml/kg tidal volume, zero PEEP and no recruitment manoeuvre. Pulmonary functions were measured pre-operatively and 12 hours after extubation. Continuous variables were analysed with the unpaired t-test and ANOVA. $P < 0.05$ was considered significant. **Results:** Final analysis was performed on 24 patients. FVC and FEV1/FVC were significantly higher in group L as compared to group H after 12 hours of extubation. ($P<0.001$) **Conclusion:** A lung-protective strategy using low tidal volume ventilation (with 10 cm H2O PEEP and RM) helped to improve lung functions 12 hours after extubation as compared to conventional high tidal volume ventilation (with zero PEEP and no RM). The overall perioperative follow up did not show any other significant differences between the two groups.

Key Words: Pulmonary functions, Lateral position, Tidal volume, urological procedure

***Address for Correspondence:**
Dr Alka Lakra, Speciality Medical Officer, Department of Anaesthesiology, Speciality Medical Officer, V N Desai Municipal General, Hospital, Mumbai, Maharashtra, INDIA.
Email: alkalakra.dr@gmail.com

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INTRODUCTION

Postoperative pulmonary complications (PPC) can occur following general anaesthesia (GA) as it alters many aspects of normal lung physiology. A wide spectrum of PPC has been reported in the literature like atelectasis, pneumonia, bronchospasm, respiratory failure with prolonged ventilation, acute lung injury including aspiration pneumonitis, acute respiratory distress syndrome etc.[1] Intraoperative mechanical ventilation(MV) in patients under GA plays an important role in the development of PPC.[2] Implementation of protective

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ventilation strategies like optimal tidal volume (V_T), positive end expiratory pressure(PEEP) and recruitment manoeuvre (RM) would reduce the incidence of PPC. The optimal settings for intraoperative MV and the role of PEEP are still debatable issues. High V_T (TV>10 ml/kg) is reported as a risk factor for prolonged MV, hemodynamic instability, higher incidence of renal failure and prolonged stay in the intensive care unit.[3] On the contrary, use of low V_T in the intraoperative period has shown to decrease pneumonia and the need for postoperative ventilatory support in patients without acute lung injury.[4] The beneficial effects of low V_T during short term ventilation have been described in the literature. But most of the studies have discussed these effects of ventilation in the supine position.[5] Change of position (supine to lateral or prone) can alter the distribution of pulmonary ventilation and perfusion.[6] In anaesthetised and paralysed patient, the lateral position leads to a decrease in functional residual capacity (FRC), changes in compliance and distribution of ventilation. Hence, this study was conceived to evaluate the effects of low V_T on lung functions in patients undergoing open urological procedures under GA in lateral position.

MATERIALS AND METHODS

This study was conducted at a tertiary care centre from November 2017 to October 2018 over a period of one year. Prior ethical permission was taken from the institutional ethical committee (No. ECARP/2017/65, dated 27.04.2017). This prospective, randomized open labelled comparative study included 30 American Society of Anaesthesiologists (ASA) physical status I and II patients, aged 18–70 years of either sex who had undergone elective open urological surgeries under GA in lateral position. Patients with cardiac diseases, ASA grade III or above, pregnant patients, body mass index > 30 kg/m^2, duration of surgery < 2 hours and those who did not cooperate or refused to participate in the study were excluded.

After a thorough pre-anaesthetic check-up, patients satisfying the inclusion criteria were selected. Patients were explained about the study protocol and written informed consent was taken from each of the 30 enrolled patients for participation in the study. Demographic data like age, weight, height and body mass index (BMI) were recorded. Preoperative chest x-ray and spirometry was done in all patients and forced vital capacity (FVC), forced expiratory volume during the first second (FEV1) and FEV1/ FVC ratio was noted. Patients were randomized on the day of surgery into one of the two groups L (i.e. low tidal volume) or H (i.e. high tidal volume) with 15 patients in each by using a computer-generated random number table. In the operation room, the standard ASA monitors were attached and baseline readings were noted. Two peripheral intravenous lines were secured and intravenous ringer lactate was started. Intravenous premedication glycopyrrolate (4µg/kg) and midazolam (0.05mg/kg) were administered. An epidural catheter was inserted before the induction of GA at the L2–L3 level for perioperative analgesia. All patients were pre oxygenated for 3 minutes with 100% O_2. GA was induced with intravenous fentanyl (2µg/kg), propofol (2 mg/kg) and atracurium (0.5 mg/kg). Patient's airway was secured with an appropriate size endotracheal tube after direct laryngoscopy. Anaesthesia was maintained with oxygen, air, the titrated dose of sevoflurane (up to MAC 2) and intermittent doses of muscle relaxant. Maintenance fluid was given at the rate of 5-6 ml/kg/hr. Patients were mechanically ventilated to maintain end-tidal carbon dioxide ($EtCO_2$) at 30-40 mm Hg using 2 lit/min flow in the closed circuit. The patient was turned to one side: right or left according to the planned side of surgery and the kidney bridge was raised slowly over five minutes with continuous haemodynamic monitoring. All patients received volume-controlled MV with a fraction of inspired oxygen (FiO2) 0.4 and the I:E ratio of 1:2. The respiratory rate (RR) was adjusted to keep normocapnia. In group L, TV was set at 5–7 ml/kg of predicted body weight (PBW) with PEEP of 10 cm H_2O while in group H, TV was at 10-12ml/kg of PBW and PEEP was zero. In group L, RM was performed directly after induction of anaesthesia, and before extubation. RM was performed by raising the limit of peak inspiratory pressure (PIP) to 45 cm of H_2O, TV at 5–7 ml/kg PBW, and RR at 6 breaths/min, PEEP at 10 cm H2O, and the I: E ratio at 2:1; then the TV was increased in steps of 4 ml/kg PBW until plateau pressure reached 30 cm H_2O and three breaths were allowed. Finally, the RR, the I: E ratio, inspiratory pause, and TV were set back to values preceding the RM, whereas the PEEP was maintained at 10 cm of H_2O. RM was used only in group L, whereas normal ventilation with high V_T was continued in group H. Intraoperatively, vital signs, core temperature, ventilator settings, FiO_2, $EtCO_2$, and airway pressures were recorded at 15 min intervals throughout the surgery. Postoperatively, patients were asked to rate their pain at rest in the supine position with 30° head end elevation on a numeric rating scale (NRS) score of 0–10 (0: no pain; 10: worst pain imaginable). If NRS score was >4, analgesia was optimized before performing spirometry. We injected 5 ml of 0.125% bupivacaine with 50 mcg fentanyl through the epidural catheter and pain score was reassessed. Measurement of pulmonary function was performed using the spirometer: before induction of anaesthesia and 12 hours after extubation. Patients received detailed instructions about how to do the tests. All measurements were taken in the supine position with 30° head end elevation. A clip was placed over the nose and the patient breathed through the mouth into a tube connected to the spirometer. First, the patient took a deep breath and then exhaled as quickly and forcefully as possible into the tube. This was done three times and the best of the three results were recorded as the measure of lung function and selected for analysis. Preoperative and postoperative chest radiographs were taken as a part of routine perioperative surgical management. Findings were scored by a radiologist unaware of group assignment using a radiological atelectasis score as follows: 0= clear lung field, 1=plate like atelectasis or slight infiltration, 2= partial atelectasis, 3=lobar atelectasis, 4=bilateral lobar atelectasis. Patient domain score (PDS) was calculated using the following four postoperative parameters: cough, temperature (38 Degree C), NRS score and atelectasis Any parameter if found present was given a score of 1. The minimum and maximum scores obtained was 1 and 4 respectively. Accordingly, the total score was used to classify the patients of the two study groups into favourable and unfavourable. Patients with a score of > 2 were classified as unfavourable and a score of <2 were classified as favourable. The sample size was calculated based on a previous study about change in pulmonary function test results with the change in V_T. [7] Considering 80.0% statistical (type II error = 0.20) and 5% type I error probability (α=0.05), the required sample size was 12 in each group. Owing to potential drop-outs, 30 patients were included in our study. Data were statistically described in terms of (mean ± SD) and percentages wherever appropriate. Continuous variables were analysed with the unpaired t-test and ANOVA. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. All statistical calculations were done using computer programs Microsoft Excel 2019 (Microsoft Corporation, NY, USA) and SPSS version 24 (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA).

RESULTS

We recruited 30 patients and 6 patients (3 patients from each group) were excluded from the final analysis because of violation of study protocol. Thus, final data analysis was performed on 24 patients. Both the groups were comparable in terms of demographic profiles (age, sex, weight, ASA physical status, BMI and operative procedures). The duration of surgery was also comparable as most of the surgeries were done by the same surgical team. The baseline pre-induction vitals in both groups were comparable. [Table 1] There was no significant difference in intra-operative data between the two groups except for V_T, $EtCO_2$ and PEEP. [Table 2] The effects of RM on HR and BP are depicted in Table 3. The HR was increased and the SBP and DBP were decreased significantly 30 minutes after RM. Pre-operative pulmonary functions such as FEV1, FVC, and FEV1/FVC showed no significant difference between groups. We found a statistically significant difference between the two groups regarding the postoperative FEV1 and the FEV1/FVC after 12 hours. [Table 4] In the postoperative follow-up, there were no significant differences between the two groups regarding the incidence of cough, fever, pain and atelectasis on chest x-ray. [Table 5] According to PDS, 91.7% of patients were with favourable outcome in group L whereas 58.3% in group H. No statistically significant difference was observed between the two groups.

Table 1: Demographic Profile

Parameters	Group H	Group L	P value
Age (year)	38.83 ± 11.2	36 ± 10.8	0.79
Sex(M/F)	8/4(66.7/33.3)	6/6(50/50)	0.4
ASA(I/II)	6/6(50/50)	7/5(58.3/41.7)	0.68
Weight (kg)	57.5 ± 6.5	56.03 ± 5.8	0.565
BMI (kg/m2)	24.31 ± 1.92	24.02 ± 1.84	0.5526
Operative Procedures			
Left Nephrectomy	3(25%)	2(16.7%)	-
Left Plyoplasty	1(8.3%)	1(8.3%)	
Right Nephrectomy	6(50%)	7(58.3%)	
Right Plyoplasty	2(16.7%)	2(16.7%)	
Pre-induction vitals:			
HR	93 ± 1.4	93.5 ± 0.70	0.284
MAP	93.82 ± 7.55	94.02 ± 7.20	0.948
SPO2	99.74 ± 0.49	99.55 ± 0.63	0.418
RR	15.02 ± 7.20	16.09 ±1.53	0.620

Table 2: Intraoperative parameters

Parameters	Group H	Group L	P-value
V_T (ml)	600 ± 141.4	325 ± 35.35	0.000
RR	12 ± 2.82	12.5 ± 2.12	0.628
PIP	20.5 ± 4.12	19 ± 1.65	0.254
EtCO2	28.5 ± 1.41	33 ± 2.12	0.000
Fluids (ml/kg/h)	7.5 ±1.53	7.0 ± 0.65	0.309
Urine output (ml/kg/h)	4 ± 2.12	4.5 ± 1.72	0.532
Duration of Surgery	128 ± 6.58	130 ± 4.32	0.388

V_T = Tidal Volume, RR = respiratory rate, PIP = peak inspiratory pressure, $EtCO_2$ = end tidal carbon dioxide, Group H = high tidal volume, Group L = low tidal volume.

Table 3: Effect of Recruitment manoeuvre in 'group L' on hemodynamic parameters

Parameters	Time			P-value
	T_0	T_1	T_{30}	
HR	84 ± 2.83	88 ± 0.70	92.5 ± 2.12	<0.001
SBP	131 ± 1.41	130.5 ± 0.70	117 ± 9.89	0.032
DBP	87.5 ± 6.36	88 ± 2.82	82.5 ± 2.12	<0.001

T0 = just before recruitment manoeuvre, T1 = one minute after recruitment manoeuvre, T_{30} = 30 minutes after recruitment manoeuvre, HR = heart rate, SBP = systolic blood pressure, DBP = diastolic blood pressure.

Table 4: Preoperative and post-operative Pulmonary Functions

PFT	Group H	Group L	P-value
	Pre-operative		
FEV1	87.5 ± 4.96	86.5 ± 2.96	0.555
FVC	94.8 ± 3.18	96.6 ± 3.28	0.179
FEV1/FVC	91.7 ± 5.32	89.2 ± 4.37	0.222
	Post-operative		
FEV1	82.1 ± 5.63	86.5 ± 2.57	0.024
FVC	95 ± 2.37	94.7 ± 3.1	0.827
FEV1/FVC	87.7 ± 5.95	90.7 ± 3.86	0.023

FVC = forced vital capacity, FEV1 = forced expiratory volume during first second, PFT =pulmonary function test, Group H = high tidal volume, Group L = low tidal volume.

Table 5: Postoperative complications

Parameters	Group H n(%)	Group L n(%)	P-value
Cough	5(41.7)	4(33.3)	1
Atelectasis	4(33.3)	1(8.3)	0.315
Fever(>38°C)	6(33.3)	3(25)	0.399
NRS (>4)	8(58.3)	6(50)	0.679
	Patient Domain Score (PDS)		
Favourable	7(58.3)	11(91.7)	0.157
Unfavourable	5(41.7)	1(8.3)	

Group H = high tidal volume, Group L = low tidal volume.

DISCUSSION

The result of the present randomized controlled trial suggests that a lung-protective strategy using low V_T with 10 cm H_2O PEEP and RM improved lung functions as compared to the conventional mechanical ventilation technique using high V_T without PEEP and RM in the first postoperative 12 hours. We did not observe any significant differences between the two groups in overall post-operative follow up. Postoperative pulmonary complications are more common in upper abdominal surgery, thoracic surgery, and urologic surgeries especially when the patient is turned to lateral position.[8] We used a lung-protective strategy during intraoperative MV, which involved the use of low VT to minimize mechanical stress, high PEEP to prevent atelectasis and RM to promote re-expansion of atelectasis. In our study, we investigated major postoperative complications with relevant clinical parameters associated with alterations in the pulmonary function. We observed a significant difference in postoperative FEV1 and FEV1/FVC between the groups.

Asida *et al.* also observed a significant difference in the pulmonary function test at 6 hrs, 12 hrs and 24 hrs following non-laparoscopic urological surgery.[7] They found better FEV1, FVC and FEV1/FVC at 6 hours, better FVC and FEV1/FVC at 12 hours and significant difference in FEV1/FVC at 24 hrs following the surgery in the low tidal volume group. In a recent Cochrane systemic review, Guay *et al.*[4] concluded that low V_T should be used preferentially during surgery. The incidence of postoperative pneumonia and prolonged ventilation was significantly reduced in patients who had received low V_T during surgery as compared to high V_T. The authors had noticed a slight decrease in hospital stay in low V_T group with no difference in 30-day mortality rate. In our study, we observed more atelectasis and unfavourable PDS in group H although it was statistically not significant.

We also evaluated the quality of analgesia through NRS score which showed no significant difference between the two groups. This could be attributed to the use of the same GA, regional anaesthesia (epidural analgesia) and multimodal analgesia protocol in both the groups. Optimal postoperative analgesia prevents under ventilation and helps in alleviating the neuroendocrine stress response. The epidural analgesia technique is proven to be superior to on-demand analgesics.[1]

There was no difference in the incidence of cough and fever (temperature >38°C) in the post-operative period between the two groups. Asida *et al.* also reported similar findings in the above-mentioned parameters.[7] Severgnini *et al.* observed statistically significant atelectasis in patients received high V_T on first and third postoperative days.[9] Our study had a few limitations. We did not compare ventilatory parameters in obese patients or patients with obstructive or restrictive lung diseases. We also did not measure lung compliance and arterial blood gas. The sample size was restricted to only 24 patients as we included only open urological procedures.

CONCLUSION

To conclude, a lung-protective strategy using low tidal volume with 5–10 cm of H20 PEEP and RM helped to improve lung functions in the first 12 hours after surgery as compared to conventional high tidal volume MV with zero PEEP and no RM. The overall perioperative follow up did not show any other significant differences between the two groups.

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