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Research Article

The Effectiveness of Lidocaine / Prilocaine Cream on Hemodynamic Parameters Following Endotracheal Tube Intubation and Postoperative Respiratory Complications in Urological Surgery in Patients During General Anesthesia

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Abstract

Background: Hemodynamic changes and postoperative respiratory complications often occurred in patients under general anesthesia by endotracheal intubation, leading to myocardial ischemia, and may increase the risk of cardiovascular and cerebrovascular diseases.

Method: This study was a prospective, randomized, placebo-controlled trial involved patients in urological surgery during general anesthesia by tracheal intubation in The Third Affiliated Hospital of The Sun Yat-sen University, China and from Jan 2014 through Dec 2018. We randomly allotted lidocaine / prilocaine cream (Ziguang Co. Ltd, Beijing, China) at a dose of 2 grams coated on the endotracheal tube or matching vaseline cream to patients. The primary efficacy outcome was hemodynamic arguments (Heart Rate (HR) and Diastolic Blood Pressure (DBP) and Systolic Blood Pressure (SBP)) following endotracheal tube intubation and postoperative cough events. Results: 501 consecutive subjects were enrolled. In test group, repeat measurement of the hemodynamic parameters during anesthesia induction and endotracheal intubation in patients were superior to that of the control group (SBP, F value = 69.216, P < 0.001; DBP, F value = 152.557, P < 0.001; HR, F value = 87.003, P = < 0.001). Significant improvement of cough events in recovery period in the test group were observed (Spontaneous cough, χ^2 value = 10.34, P = 0.001; Induces cough, χ^2 value =10.41, P = 0.001). Conclusion: our findings represent the first evidence from a randomized controlled trial that evaluates the effect of lidocaine / prilocaine cream coated on the endotracheal tube in patients for urological surgery. (ClinicalTrials.gov number, NCT02017392.)

Background: Hemodynamic changes and postoperative respiratory complications often occurred in patients under general anesthesia by endotracheal intubation, leading to myocardial ischemia, and may increase the risk of cardiovascular and cerebrovascular diseases [1]. At the same time, it also interferes with the allocation of medical staff. Lidocaine / prilocaine cream, a eutectic mixture (1:1) of local anesthetics including 2.5% lidocaine and 2.5% prilocaine which has been used as a partial anesthetic [2-4]. Lidocaine / prilocaine cream produces local anesthesia to the mucosa by releasing lidocaine and prilocaine in the form of base to the submucosa up to 5 mm deep and by accumulating at the mucosal pain receptors and nerve endings. To our knowledge, no high-quality randomized controlled study of lidocaine / prilocaine cream in preventing hemodynamic changes and postoperative respiratory complications in patients who go through tracheal intubation under general anesthesia has been reported. This project intends to carry out a randomized controlled trial on the application of lidocaine / prilocaine cream in urological surgery in patients during general anesthesia by tracheal intubation. It can provide accurate evidence for the local use of lidocaine / prilocaine cream in tracheal intubation of patients undergoing general anesthesia, and improve the complications and quality of life of patients.

Methods

Patients

Patients were enrolled in the trial if they had been arranged for urological surgery by general anesthesia using endotracheal tube intubation. Major exclusion includes allergies to lidocaine, prilocaine or other ingredient of the test materials; with ischemic heart disease or kidney dysfunction and ASA grade IV.

Trial Design

This study was a prospective, randomized, placebo-controlled trial involved patients in urological surgery during general anesthesia by tracheal intubation in the Third Affiliated Hospital of The Sun Yat-sen University, China and from Jan 2014 through Dec 2018. We randomly allotted lidocaine / prilocaine cream (Ziguang Co. Ltd, Beijing, China) at a dose of 2 grams coated on the endotracheal tube or matching vaseline cream using a computer-generated random number software to patients. The primary efficacy outcome was hemodynamic arguments (HR, DBP and SBP)) following endotracheal tube intubation and postoperative respiratory complications (cough events). The protocol was upheld by The Third Affiliated Hospital of the Sun Yet-sen University's Ethics Committee. Patients were informed and written consents were given before the study. Patients, investigators and study administrators were all unaware of the patient's trial-group assignments

Statistical Analysis

Data analysis was implemented by using R version 3.0.2. According to result of a prior analysis of 10 patients in each group and the intention-to-treat principle, power of analysis calculation ($\alpha = 0.05$, $1 - \beta = 0.8$ and sample dropout rate = 20%) was set. The minimum sample size of 150 cases in each group (totally of 300 cases) was calculated by the Open Epi Version 2 software [5]. The independent t test was used as a tool which compares the 2 groups, whereas Chi-square test was used for analyzing categorical data. Repeated measures ANOVA test was used for repeated measurement data. A value of $P < 0.05$ was considered statistically significant.

Results

Patients

Between Jan, 2014, and Dec, 2018, we enrolled 501 consecutive subjects (50.3 [SD 5.7] years, 49.1% women) of whom had been arranged for urological surgery by general anesthesia using endotracheal tube intubation in the Third Affiliated Hospital of Sun Yat-sen University. Age, gender, ASA rating and operation time were similar in the two groups ($P > 0.05$ respectively) (Table 1).

	Test Group	Control Group	t/χ^2 Value	P Value
Age (years)	50.5±5.7	50.0±5.6	0.704	0.482
Gender (male n (%))	71(46.4)	82(53.6)	1.463	0.226
ASA I (%)	61(51.3)	58(48.7)	0.191	0.909
ASA II (%)	49(49.5)	50(50.5)		
ASA III (%)	40(48.2)	43(51.8)		
Operation time (hours)	1.4±0.5	1.4±0.6	0.429	0.668

Table 1: Baseline' Characteristics.

Primary End Point

In test group, repeat measurement of the hemodynamic parameters (SBP, DBP and HR) during anesthesia induction and endotracheal intubation in patients were superior to that of the control group (SBP, F value = 69.216, P < 0.001; DBP, F value = 152.557, P < 0.001; HR, F value = 87.003, P = < 0.001) (Table 2).

	Group	Before induction	Before intubation	Instant intubation	1 minute after intubation	3 minute after intubation	Instant extubation	1 minute after extubation	3 minute after extubation	F Value	P Value
SBP(mmHg)	Test group	144.1±5.7	133.1±5.1	128.1±4.7	126.1±4.3	126.1±4.0	125.1±3.8	122.1±3.5	120.0±3.3	69.216	<0.0001
	Control group	141.5±5.4	134.5±5.0	132.5±4.6	131.6±4.2	129.6±4.0	131.6±3.7	128.6±3.5	127.6±3.3		
DBP(mmHg)	Test group	83.1±5.7	76.1±5.1	75.1±4.7	75.1±4.3	74.1±4.0	72.0±3.8	71.1±3.5	71.0±3.3	152.557	<0.0001
	Control group	85.50±5.4	76.5±5.0	80.5±4.6	79.6±4.2	80.6±4.0	86.1±3.7	81.6±3.5	80.6±3.3		
HR(beat/min)	Test group	85.1±5.7	77.1±5.1	83.1±4.7	82.1±4.3	81.1±4.0	82.0±3.8	82.1±3.5	81.0±3.3	87.003	<0.0001
	Control group	87.5±5.4	78.5±5.0	88.5±4.6	87.6±4.2	85.6±4.0	89.6±3.7	87.6±3.5	85.6±3.3		
*SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; HR: Heart Rate; min: Minute.											

Table 2: Comparison of hemodynamic parameters between two groups.

Significant improvement of cough events in recovery period in the test group were observed (Spontaneous cough, χ^2 value = 10.34, P = 0.001; Induces cough, χ^2 value =10.41, P = 0.001) (Table 3).

	Test Group	Control Group	χ^2 Value	P Value
Spontaneous cough [case (%)]	4(2.6)	13(8.9)	10.34	0.001
Induces cough [case (%)]	7(4.7)	18(12.0)	10.41	0.001

Table 3: Comparison of cough events in recovery period between two groups.

Discussion

Hemodynamic parameters during anesthesia induction and endotracheal intubation in patients undergone general anesthesia should be kept stable [6]. The stimulating effect of endotracheal intubation during general anesthesia on pharynx, larynx and trachea result in sympathetic nerve excitation, leading to complications in cardiovascular and cerebrovascular system [7]. Our data show that in patients in urological surgery by general anesthesia using endotracheal tube intubation, hemodynamic parameters and cough events were improved by lidocaine / prilocaine cream coated on the endotracheal tube. Our results are consistent with the finding in Chen YQ [8] for elderly patients.

The mechanism of lidocaine / prilocaine cream in preventing cardiovascular stress reaction in patients undergoing tracheal intubation under general anesthesia includes: 1) good safety, no serious adverse reactions were found in literatures; 2) effective in 2 minutes and lasting for 4-6 hours; 3) complete absorption of drugs with few residues, which does not affect tracheal ciliary movement; 4) The drug itself has no bacterial growth; no flow, easy to apply and clean; 5) the drug exists in the form of oil in water, which meet the lubrication effect of catheter implantation [9,10].

There are strengths of our trial. First, well- designed RCT. Second, promising results. We have limitations too. First, the obervation period in our study is short. Second, the safety of our treatment did not ruled out side effects.

Conclusion

Our findings represent the first evidence from a randomized controlled trial that evaluates the effect of lidocaine / prilocaine cream coated on the endotracheal tube in patients for urological surgery.

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