

## An Observational Study on the Short Term ADRS of Salbutamol Inhalation in Pulmonary Infections

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### ABSTRACT

An observational study on short term ADRs of salbutamol inhalation in pulmonary infection. To analyze the short term ADRs of salbutamol inhalation in pulmonary infections associated with diabetic condition. To evaluate the percentage of occurrence of tachycardia and hypoglycemia post admission of salbutamol inhalation. To compare the variation of blood sugar in diabetic and non diabetic patients. Compare the impact of various devices in including suspected the entire study was planned to be period of six months. Among the study populations, the male patients at the age of 30-40yrs uses inhaler device and the female patients at the age 30-40yrs uses inhaler device. Nebulizer device was minimumly susceptible to ADR and this study can be performed in large sample for better interaction.

### I. INTRODUCTION

Short acting beta2 agonists (SABAs) such as salbutamol are well known as the first-line therapy for the treatment of acute exacerbations, exercise-induced asthma and childhood intermittent asthma. As needed, SABAs with no controller should be considered only if symptoms are rare and there is no awakening due to asthma. Salbutamol, through its effects of relaxing airway smooth muscle and increasing airflow, provides rapid relief of acute asthma symptoms. Treatment's effects begin in about 10-15 minutes and peak effect is usually within 30 minutes.

Hypoglycemia is most often seen in patients who have diabetes that undergoing pharmacologic intervention. Among this group, patients with type 1 diabetes are three times as likely to experience hypoglycemia than patients with type 2 diabetes when receiving treatment.

### METHODOLOGY

Study Design : Prospective Observational Study.

Study Duration: 6 months

Study location: Sudha multi-speciality Tertiary care Hospital, Perundurai road, Erode.

Study population: 150 subjects

### INCLUSION CRITERIA :

Patients with respiratory infections only .  
Patient with respiratory infection and diabetes.  
Male and female patients are 10 to 70 age group.

### EXCLUSION CRITERIA:

Pregnant women  
Psychiatric patient  
Patient with chronic diseases namely hypertension, CAD.

### PLAN FOR WORK

Step 1: Literature review  
Step 2: Problem identification for microsoft  
Step 3: Obtain ethics committee approval  
Step 4: Selection of patient based on inclusion criteria  
Step 5: Data collection  
Step 6: Data entry  
Step 7: Data analysis  
Step 8: Interpretation, report preparation and submission

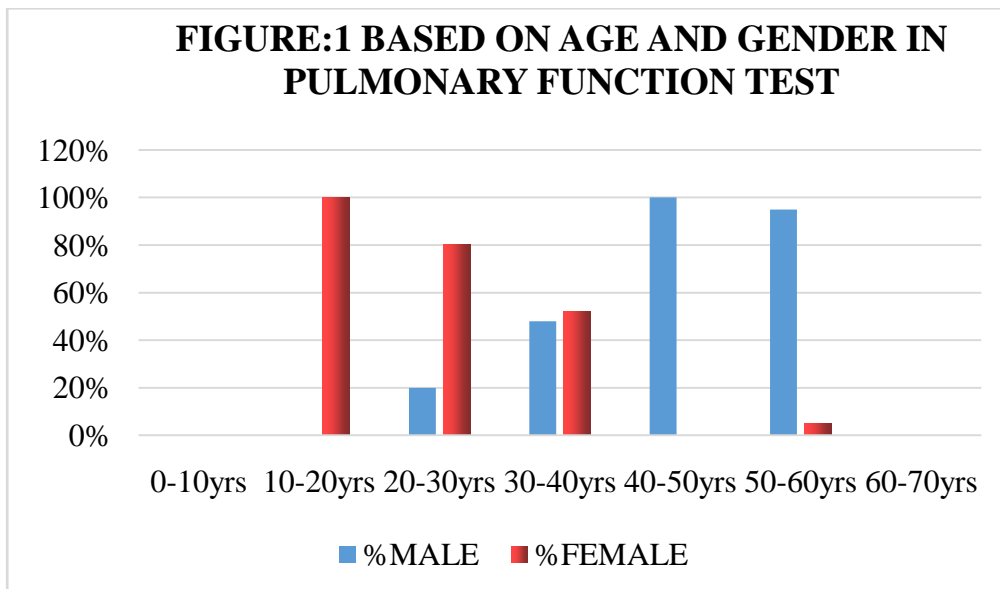
### PLAN FOR ANALYSIS

To analyze the short-term ADRs of salbutamol inhalation in pulmonary infection associated with diabetic condition. To evaluate the percentage of occurrence of tachycardia and hypoglycemia post administration of salbutamol inhalation in the study population of pulmonology department. To compare the variation in blood sugar in diabetic and non-diabetic patient. Compare the impact of various devices in inducing suspected ADRs. From the patients by using collect the data and analysing the data and the statistical analysis to be performed and the results were tabulated and compared globally.

## II. RESULTS

**TABLE:1 BASED ON AGE AND GENDER IN PULMONARY FUNCTION TEST**

AGE	%MALE	%FEMALE
0-10yrs	-	-
10-20yrs	-	100%
20-30yrs	20%	80%
30-40yrs	48%	52%
40-50yrs	100%	-
50-60yrs	95%	5%
60-70yrs	-	-

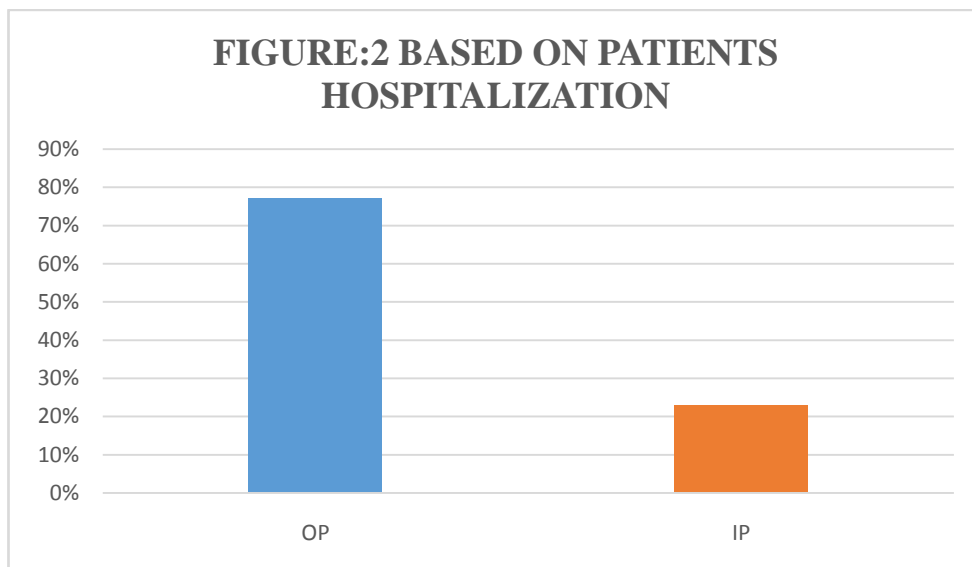


The most of the patients are affected by the 40 to 50 age groups of male patients and also most of the patients are affected by the 10 to 20 age

group of female patients. Less patients are affected by the age group 20 to 30 and female age group 50 to 60.

**TABLE:2 BASED ON PATIENTS HOSPITALIZATION**

PATIENTS	PERCENTAGE
OP	77%
IP	23%



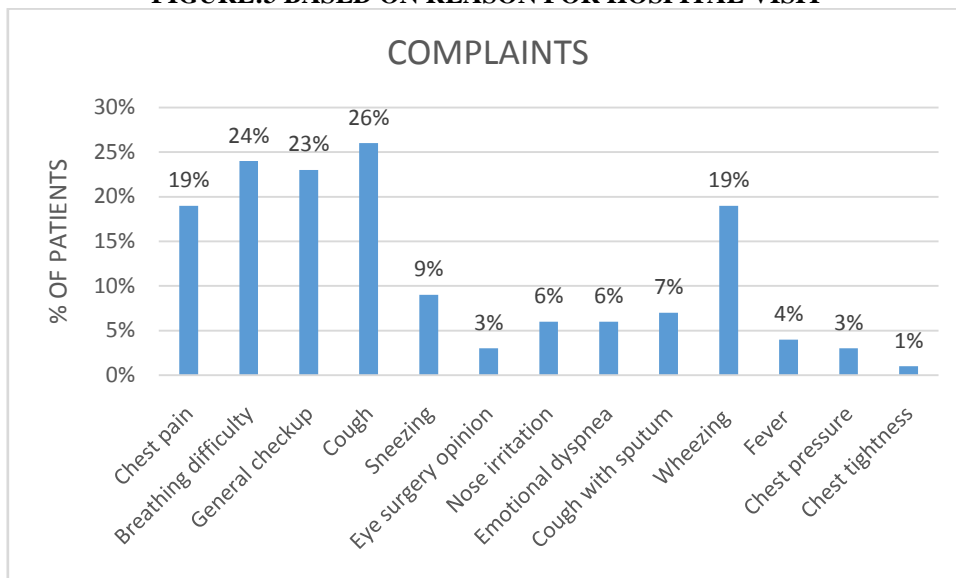
Compares the inpatients and outpatients in the hospital. Maximum number of patients suffering from pulmonary infections observed in the outpatients. compare to inpatients and

outpatients, outpatients are the more than inpatients. The percentage of inpatients rate is 23 percentage and outpatients rate is 77percentage.

**TABLE :3 BASED ON REASON FOR HOSPITAL VISIT**

COMPLAINTS	PERCENTAGE
Chest pain	19%
Breathing difficulty	24%
General checkup	23%
Cough	26%
Sneezing	9%
Eye surgery opinion	3%
Nose irritation	6%
Emotional dyspnea	6%
Cough with sputum	7%
Wheezing	19%
Fever	4%
Chest pressure	3%
Chest tightness	1%
Total number of cases	150

**FIGURE:3 BASED ON REASON FOR HOSPITAL VISIT**



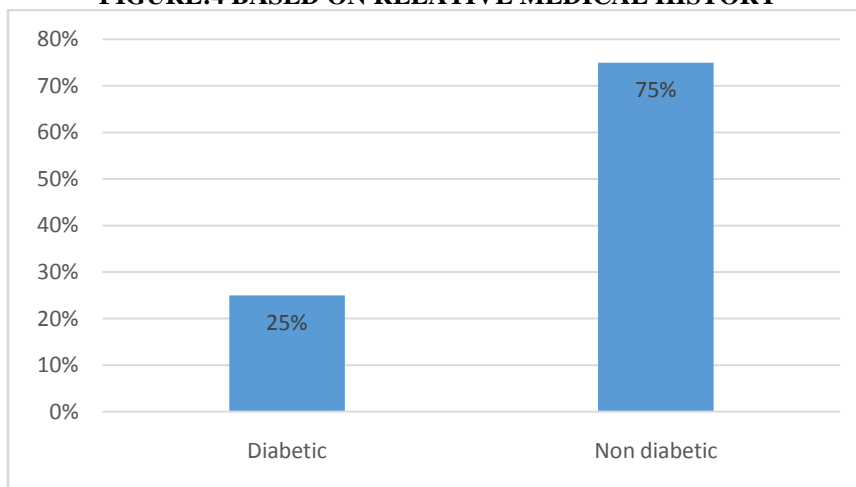
Among the study population , Patients are admitted in the complaints of Cough ,breathing difficulty and general checkup, nose irritation, chest pressure, wheezing, chest tightens, cough,

sneezing,chest pain.. most complaints are involved in the cough, breathing difficulty, general checkup compare to other complaints.

**TABLE :4 BASED ON RELATIVE MEDICAL HISTORY**

PAST MEDICAL HISTORY	PERCENTAGE
Diabetic	25%
Non diabetic	75%

**FIGURE:4 BASED ON RELATIVE MEDICAL HISTORY**



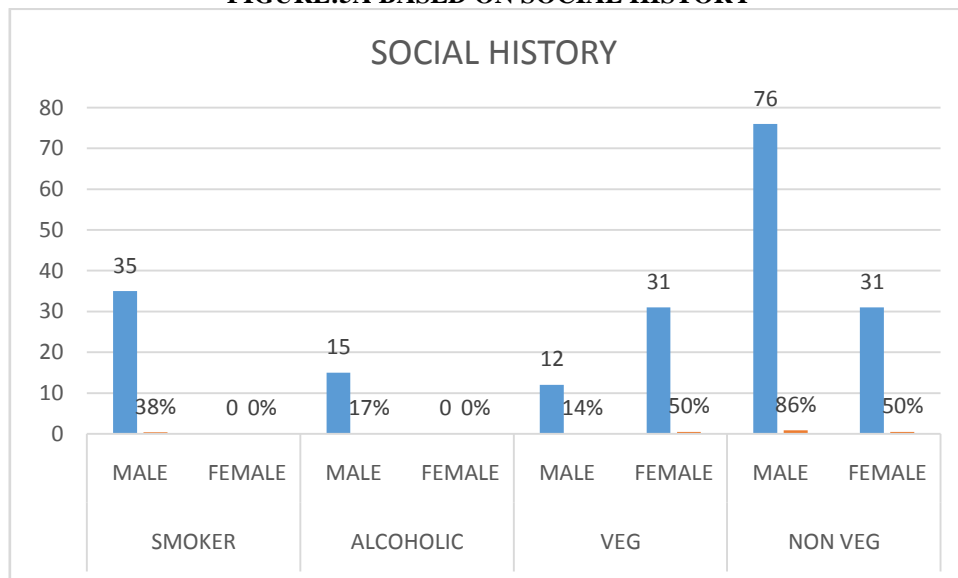
Among the study population, compare diabetic patient and non diabetic patient relative medical

history ,Most of the patients are involved in the study non-daibetic conditions

**TABLE :5A BASED ON SOCIAL HISTORY**

SMOKER		ALCOHOLIC		DIET			
				Veg		Non -veg	
MALE	FEMALE	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
35	0	15	0	12	31	76	31
38%	0%	17%	0%	14%	50%	86%	50%

**FIGURE:5A BASED ON SOCIAL HISTORY**

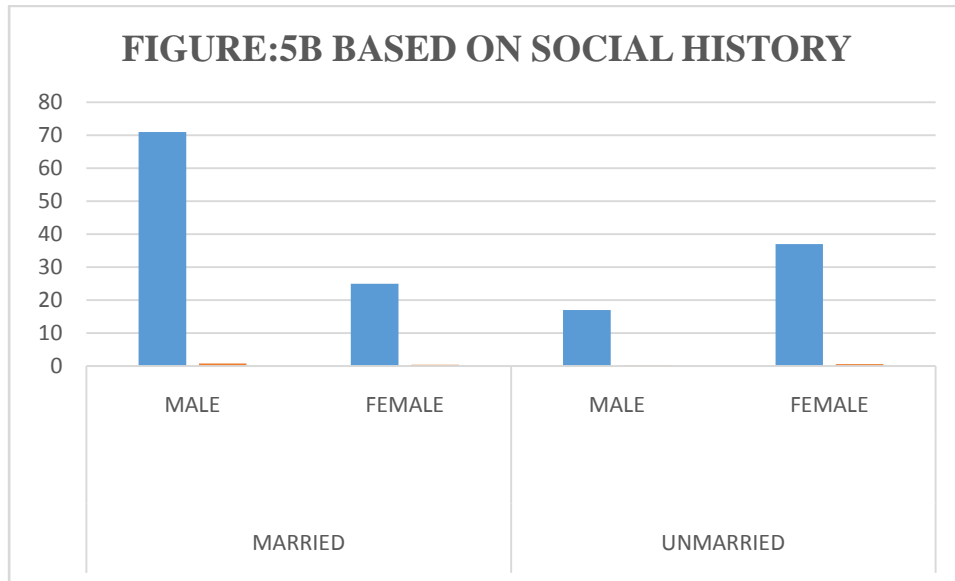


Among the study population, social history was classified three categories like smoking patients, non-smoking patients, diet condition of the patients. We analyse the study of patients with pulmonary infections, Male patients have smoking

and alcohol. Female patients have not smoking and alcohol in this study. The study populations of male patients are more non-veg compare to the non-veg female patients.

**TABLE:5B BASED ON SOCIAL HISTORY**

MARRIED		UNMARRIED	
MALE	FEMALE	MALE	FEMALE
71	25	17	37
81%	40%	19%	60%

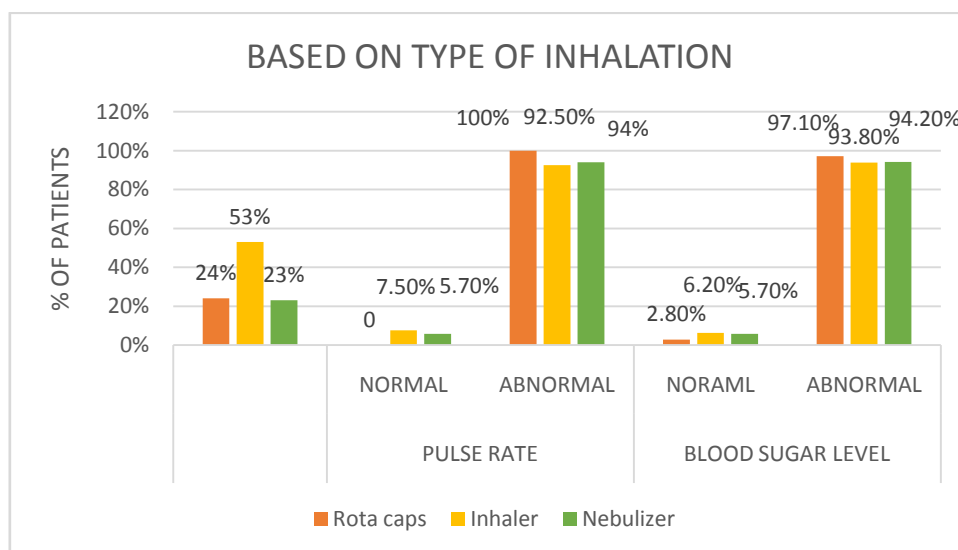


Among the study population, compare the married patients and unmarried patients based on the social history. Married patients are mostly male

patients and unmarried patients are mostly female patients.

TABLE :6 BASED ON TYPE OF INHALATION

TYPE OF INHALATION	PERCENTAGE	PULSE RATE		BLOOD SUGAR LEVEL	
		NORMAL	ABNORMAL	NORMAL	ABNORMAL
Rota caps	24%	-	100%	2.8%	97.1%
Inhaler	53%	7.5%	92.5%	6.2%	93.8%
Nebulizer	23%	5.7%	94%	5.7%	94.2%



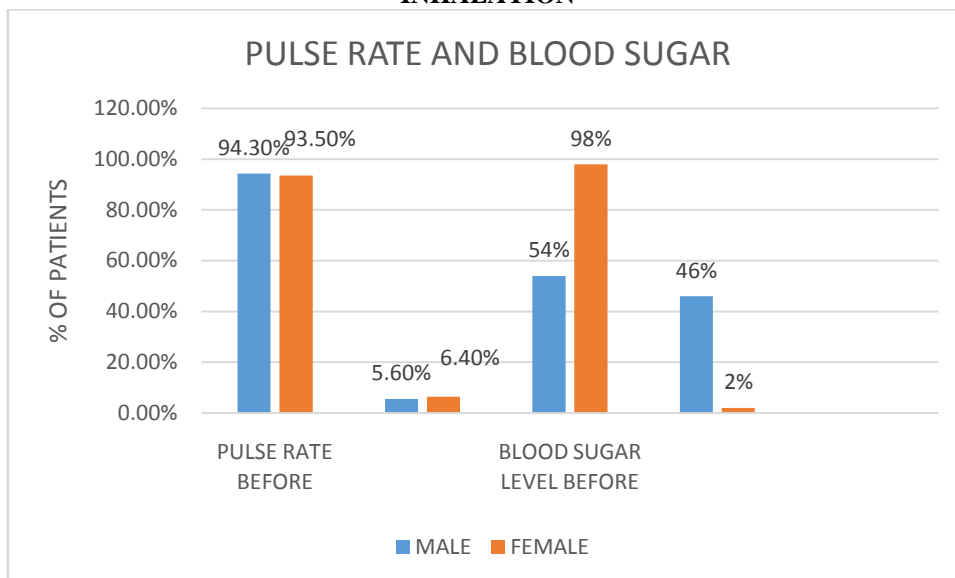
From the patient by using inhaler device's percentage rate is high Compare to the nebulizer and rotcaps. Because of inhaler salbutamol

administration device was easily using method of the device .Patients was less commonly used Salbutamol administration rotacaps Device.

**TABLE :7 BASED ON PULSE RATE AND BLOOD SUGAR LEVEL BEFORE SALBUTAMOL INHALATION**

GENDER	PULSE RATE BEFORE		BLOOD SUGAR LEVEL BEFORE	
	NORMAL	ABNORMAL	NORMAL	ABNORMAL
Male	94.3%	5.6%	54%	46%
Female	93.5%	6.4%	98%	2%

**FIGURE: 7 BASED ON PULSE RATE AND BLOOD SUGAR LEVEL BEFORE SALBUTAMOL INHALATION**



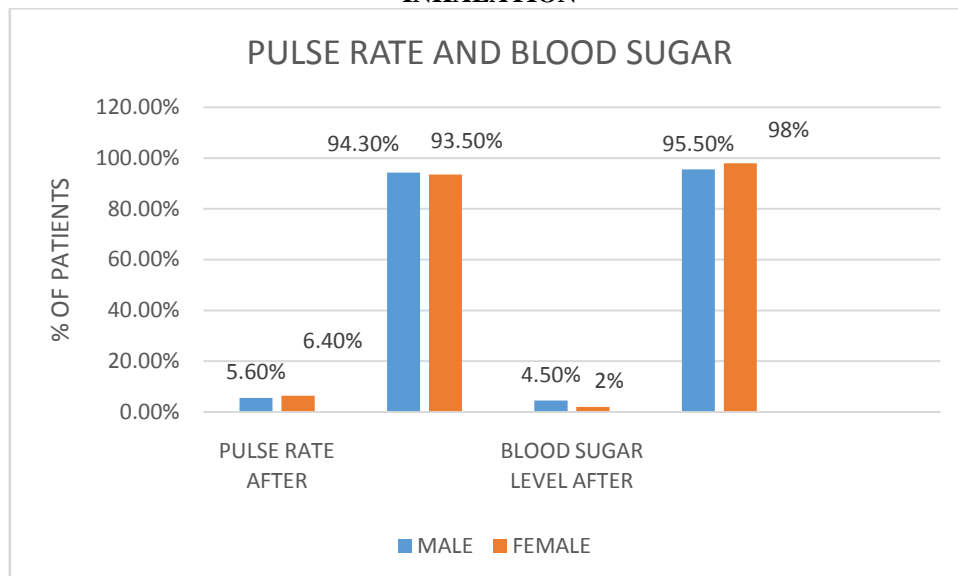
Among the study population, study subjects are before salbutamol administration of male patients are normal pulse rate compare to the female patients.

The before salbutamol administration of female patients are normal blood sugar level compare to the male patients.

**TABLE :8 BASED ON PULSE RATE AND BLOOD SUGAR LEVEL AFTER SALBUTAMOL INHALATION**

GENDER	PULSE RATE AFTER		BLOOD SUGAR LEVEL AFTER	
	NORMAL	ABNORMAL	NORMAL	ABNORMAL
Male	5.6%	94.3%	4.5%	95.5%
Female	6.4%	93.5%	2%	98%

**FIGURE:8 BASED ON PULSE RATE AND BLOOD SUGAR LEVEL AFTER SALBUTAMOL INHALATION**



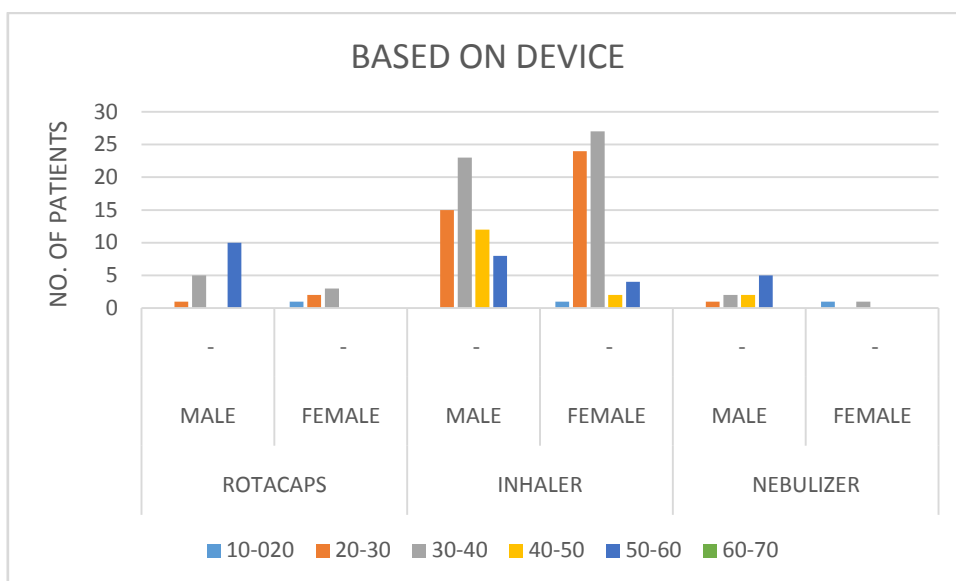
Among the study population, study subjects are after salbutamol administration of male patients are abnormal pulse rate compare to the female patients.

The after salbutamol administration of female patients are abnormal blood sugar level compare to the male patients.

**TABLE :9 BASED ON DEVICE**

AGE IN YEARS	ROTACAPS		INHALER		NEBULIZER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
0-10	-	-	-	-	-	-
10-20	-	1	-	1	-	1
20-30	1	2	15	24	1	-
30-40	5	3	23	27	2	1
40-50	-	-	12	2	2	-
50-60	10	-	8	4	5	-
60-70	-	-	-	-	-	-





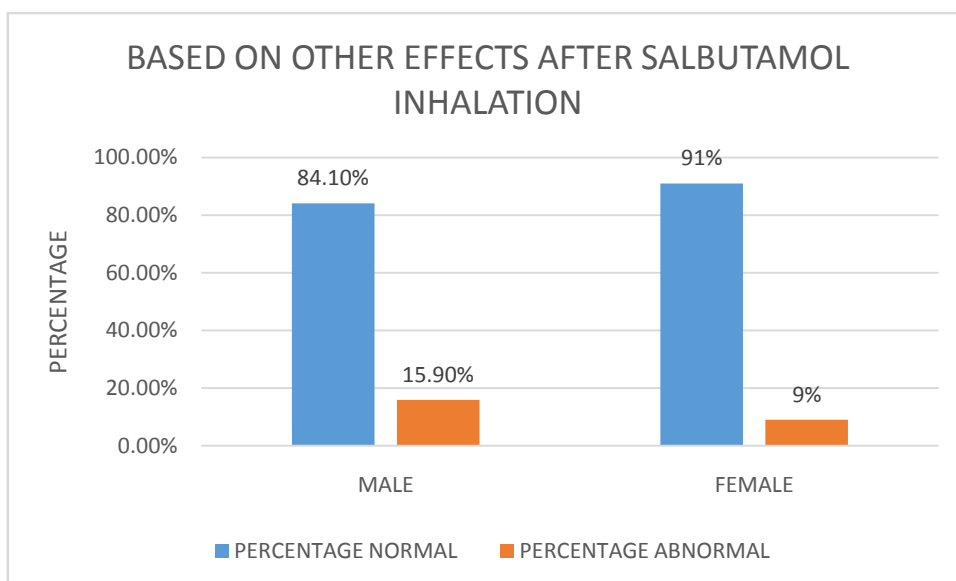
Among the study population, the study subjects of 50 to 60 age group male patients are highly used in rotacaps compare to the another age groups.

The study subjects of 30 to 40 female patients are mostly used in inhaler compare to the another age groups.

The study subjects of 50 to 60 male patients are highly used in nebulizer compare to the another age groups.

**TABLE :10 BASED ON OTHERS EFFECTS OF AFTER SALBUTAMOL INHALATION**

OTHERS	PERCENTAGE	
	NORMAL	ABNORMAL
Male	84.1%	15.9%
Female	91%	9%



Among the study population ,other effects of after salbutamol inhalation was palpitations, swelling, pain,trembling,heasache.In this study, other effects of after salbutamol inhalation to compare male patients and female patients, male patients are more occurs compare to the female patients.

### III. DISCUSSION

Salbutamol is a beta-2 agonist and is widely used as a bronchodilator in the treatment of patients with bronchial asthma and COAD. We aimed to analyze the acute effects of salbutamol inhalation. Our results shows that salbutamol nebulizer, rotacaps,inhalerleads to a significant increase in the heart rate and blood sugar level as compared to diabetic and non diabetic patients. The dose used in our study was lesser than the commonly used clinical dose (2mg). This indicates that tachycardiaand hypoglycemiais a significant even at lower doses.

Total number of volunteers were found to be 150 percentage,number of male volunteers were found to be 87 percentage,number of female volunteers were found to be 63 percentage. Volunteers used salbutamol administration devices was inhaler, rotacaps, nebulizerNumber of volunteers were used to be inhaler device was 53 percentage,number of volunteers were used to be rotacaps 24 percentage, number of volunteers were used to be nebulizer 23 percentage.Most of the volunteers in the study,commonly used to be inhaler device compared to nebulizer and rotacaps. In tachycardia occurs, male volunteers were found to be 94.3percent and female volunteers were found to be 93.5 percentage.Inhypoglycemia occurs, male volunteers were found to be 95.5percent and female volunteers were found to be percentage 98 percentage.

### IV. CONCLUSION

The study was initiated from literature review,concept identification selection of volunteers in accords with pre-fixed inclusion and exclusion criteria.Among thestudy populations, the male patients at the age of 30-40yrs uses inhaler device and the female patients at the age of 30-40yrs uses inhaler device.Nebulizer device was minimumly susceptible to ADR and this study can be performed in larger sample for better interaction

### REFERENCE

[1]. Omar Farooq nafen al Azzawi ,et al .The effect of nebulized salbutamol on serum

potassium and blood sugar level of asthmatic patients .Global Journal of health sciences ,vol .10 ,no .9(2018) , DOI : 10.5539/gjhs.v10n9p25 .

- [2]. Salman A Azzawi al. Short –term effect of inhaled salbutamol on heart rate in healthy volunteers.Cureus.2001 mar;13(3):e13672.
- [3]. Stephen j fowler ,et al .Pharmacokinetics and systemic B2 adrenoreceptor-mediated response to inhaled salbutamol j clin pharmacol.2001 par :51(4):359-362 .DOI:10.1046
- [4]. Leyla cekici et.al 2009 conducted short term effect of inhaled salbutamol on autonomic cardiovascular control in healthy volunteers.British pharmacology society. 2009April, 67(4),392-402.
- [5]. Stephanie Woodward et.al 2015 conducted SVT after inhaled short acting beta agonist treatment in children. J asthma 2021 April,58(4),471-480.doi 10.1080/02770393.2019.
- [6]. N. Ullmann et.al salbutamol and around Published online 2015 seep 30.doi .10.1186/1824-7288-s2-A74.Italian journal of paediatrics.
- [7]. Thomas M et.al conducted upper respiratory Tract infection. Published on June 30,2021.Journal stat pearls publishing Treasurable(Fl).
- [8]. The Global Initiative for Asthma (GINA) Resources include Pocket Guide for Asthma Management and Prevention, and GINA Report, Global Strategy for Asthma Management and Prevention. <http://www.ginasthma.org> (Updated 2015)
- [9]. Starkey ES, Mulla H, Sammons HM, Pandya HC. Intravenous salbutamol for childhood asthma: evidence-based medicine Arch Dis Child. 2014;99(9):873–877. doi: 10.1136/archdischild-2013-304467. [PubMed] [CrossRef] [Google Scholar]
- [10]. Cates CJ, Jaeschke R, Schmidt S, Ferrer M. Regular treatment with salmeterol and inhaled steroids for chronic asthma: serious adverse events. Cochrane Database Syst Rev. 2013;3:CD006922. [PubMed] [Google Scholar]
- [11]. Sellers WF. Inhaled and intravenous treatment in acute severe and life-threatening asthma. Br J Anaesth. 2013;110(2):183–190. doi: 10.1093/bja/aes444 .

- [12]. Hindle M, Chrystyn H. Determination of the relative bioavailability of salbutamol to the lung following inhalation. *Br J Clin Pharmacol*. 1992;34(4):311–5.
- [13]. Du X-L, et al. Pharmacokinetics and relative bioavailability of salbutamol metered-dose inhaler in healthy volunteers. *Acta Pharmacol Sin*. 2002;23(7):663–6. CAS, pubmed
- [14]. Hindle M, et al. Relative bioavailability of salbutamol to the lung following inhalation via a novel dry powder inhaler and a standard metered dose inhaler. *Br J Clin Pharmacol*. 1997;43(3):336–8.
- [15]. Whale CI, Sovani MP, Mortimer KJ, Harrison TW, Tattersfield AE. Systemic and bronchodilator effects of inhaled rac-formoterol in subjects with chronic obstructive pulmonary disease: A dose-response study. *Br J Clin Pharmacol*. 2007;65:841–7.
- [16]. Singhania N, Dhamija R, Lodha R, Kabra SK. Salmeterol Vs Formoterol: A comparison of rapid bronchodilator effect in a randomised controlled trial. *Indian Pediatr*. 2008;45:225–8.
- [17]. Seberova E, Anderson A. Oxis (formoterol given by Turbuhaler) showed as rapid an onset of action as salbutamol given by pMDI. *Respir Med*. 2000;94:607–11.
- [18]. Malolepszy J, Boszormenyi Nagy G, Selroos O, Larsson P, Brander R. Safety of formoterol Turbuhaler at cumulative dose of 90 µg in patients with acute bronchial obstruction. *Eur Respir J*. 2001;18:928–34.
- [19]. Tattersfield AE. Clinical pharmacology of long acting (beta) - receptor agonists. *Life Sci*. 1993;52:2161–9. [PubMed] [Google Scholar]
- [20]. Wegener T, Hedenstrom H, Melander B. Rapid onset of action of inhaled formoterol in asthmatic patients. *Chest*. 1992;102:535–8. [PubMed] [Google Scholar]
- [21]. Hospenthal MA, Peters JI. Long acting β<sub>2</sub>-agonists in the management of asthma exacerbations. *Curr Opin Pulm Med*. 2005;11:69–73.
- [22]. Bateman ED, Hurd SS, Barnes PJ, Bousquet J, Drazen JM, Fitz Gerald M, et al. Global strategy for asthma management and prevention. GINA executive summary. *Eur Respir J*. 2008;31:143–78.
- [23]. GlaxoSmithKline UK. (2015) Ventolin nebula 2.5 mg, 5 mg. <http://www.medicines.org.uk/emc/medicine/102>. Accessed 2016 Mar. 29.
- [24]. Teva Pharmaceuticals. Salami STERIS-Neb 5 mg/2.5 mL nebuliser solution. 2014. West Yorkshire, UK, Teva Pharmaceuticals Europe B.V.
- [25]. GlaxoSmithKline UK. (2015) Vent Olin® Respirator® Solution 5 mg/milk <https://www.medicines.org.uk/emc/medicine/103>. Accessed 2016 Mar 29.
- [26]. Szafranski W, Cukies A, Ramirez A, Manga G, Sensors R, Nahabedian S, et al. (2003) Efficacy and safety of budesonide/formoterol in the management of chronic obstructive pulmonary disease. *Eur Respir J* 21: 74–81.
- [27]. Calverley PM, Boonsawat W, Cseke Z, Zhong N, Peterson S, Olsson H. (2003) Maintenance therapy with budesonide and formoterol in chronic obstructive pulmonary disease. *Eur Respir J* 22: 912–919.
- [28]. Anzueto A. (2010) Impact of exacerbations on COPD. *Eur Respir Rev* 19: 113–118. doi: 10.1183/09059180.00002610.
- [29]. Scichilone N, Basile M, Battaglia S, Bellia V. (2014) What proportion of chronic obstructive pulmonary disease outpatients is eligible for inclusion in randomized clinical trials? *Respiration* 87: 11–17. doi: 10.1159/000355082.
- [30]. Cekici L, Valipour A, Kohansal R, Burghuber OC: Short-term effects of inhaled salbutamol on autonomic cardiovascular control in healthy subjects: a placebo-controlled study. *Br J Clin Pharmacol*. 2009, 67:394-402. 10.1111/j.1365-2125.2009.03377
- [31]. Jartti T, Kaila T, Tahvanainen K, Kuusela T, Vanto T, Välimäki I: The acute effects of inhaled salbutamol on the beat-to-beat variability of heart rate and blood pressure assessed by spectral analysis. *Br J Clin Pharmacol*. 1997, 43:421-428. 10.1046/j.1365-2125.1997.00565
- [32]. Dayimi Kaya, Irfan Barutcu, Ali Metin Esen, et al.: Comparison of the effects of ipratropium bromide and salbutamol on autonomic heart rate control. *EP Europace*. 2004, 6:602-607. 10.1016/j.eupc.2004.07.010
- [33]. Zitek T, Cleveland N, Rahbar A, et al.: Effect of nebulized albuterol on serum lactate and potassium in healthy subjects.

- AcadEmerg Med. 2016, 23:718-721. 10.1111/acem.12937
- [34]. Waddell JA, Emerson PA, Gunstone RF: Hypoxia in bronchial asthma. *BMJ*. 1967, 2:402-404. 10.1136/bmj.2.5549.402
- [35]. Kamble S, Bharmal M. Incremental direct expenditure of treating asthma in the United States. *J Asthma*. 2009;46(1):73–80. doi: 10.1080/02770900802503107.
- [36]. Asher I, Pearce N. Global burden of asthma among children. *Int J Tuberc Lung Dis*. 2014;18(11):1269–78. doi: 10.5588/ijtld.14.0170.
- [37]. Global Initiative for Asthma (GINA). 2019.
- [38]. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. NIH. 2007.
- [39]. Wang J. Efficacy of Ipratropium Bromide Combined with Salbutamol Atomization Inhalation in Treating Bronchial Asthma with Pulmonary Infection in Children. *Journal of North Pharmacy*. 2019(04):52–3.
- [40]. Qureshi F, Pestian J, Davis P, Zaritsky A. Effect of nebulized ipratropium on the hospitalization rates of children with asthma. *N Engl J Med*. 1998;339(15):1030–5. doi: 10.1056/NEJM199810083391503.
- [41]. Memon BN, Parkash A, Ahmed Khan KM, Gowa MA, Bai C. Response to nebulized salbutamol versus combination with ipratropium bromide in children with acute severe asthma. *J Pak Med Assoc*. 2016;66(3):243–6.
- [42]. Watanasomsiri A, Phipatanakul W. Comparison of nebulized ipratropium bromide with salbutamol vs salbutamol alone in acute asthma exacerbation in children. *Annals of Allergy, Asthma and Immunology*. 2006;96(5):701–6. doi: 10.1016/S1081-1206(10)61068-X.
- [43]. Rodrigo GJ, Castro-Rodriguez JA. Anticholinergics in the treatment of children and adults with acute asthma: a systematic review with meta-analysis. *Thorax*. 2005;60(9):740–6. doi: 10.1136/thx.2005.040444.
- [44]. Nibhanipudi K, Hassen G, Smith A. Beneficial effects of warmed humidified oxygen combined with nebulized albuterol and ipratropium in pediatric patients with acute exacerbation of asthma in winter months. *Journal of emergency medicine*.
- [45]. Sharma A, Madaan A. Nebulized salbutamol vs salbutamol and ipratropium combination in asthma. *Indian J Pediatr*. 2004;71(2):121–4. doi: 10.1007/BF02723090.
- [46]. Anthracopoulos MB, Karatza AA, Davlouros PA, Chiladakis JA, Manolis AS, Beratis NG. Effects of two nebulization regimens on heart rate variability during acute asthma exacerbations in children. *Journal of Asthma*. 2005;42(4):273–9. doi: 10.1081/jas-200057895.
- [47]. Ducharme FM, Davis GM. Randomized controlled trial of ipratropium bromide and frequent low doses of salbutamol in the management of mild and moderate acute pediatric asthma. *Journal of Pediatrics*. 1998;133(4):479–85. doi: 10.1016/s0022-3476(98)70054-x.
- [48]. Travers AH, Milan SJ, Jones AP, Camargo CA Jr, Rowe BH. Addition of intravenous beta(2)-agonists to inhaled beta(2)-agonists for acute asthma. *Cochrane Database Syst Rev*. 2012;(12):CD010179.
- [49]. Boulton DW, Fawcett JP. Enantioselective disposition of salbutamol in man following oral and intravenous administration. *Br J Clin Pharmacol*. 1996;41:35–40.
- [50]. Shann F. Dose of intravenous infusions of terbutaline and salbutamol. *Crit Care Med*. 2000;28:2179–80.
- [51]. Qureshi F, Pestian J, Davis P, Zaritsky A. Effect of nebulized ipratropium on the hospitalization rates of children with asthma. *N Engl J Med*. 1998;339:1030–5.
- [52]. Evans ME, Paterson JW, Richards AJ, Walker SR. Pharmacokinetics of inhaled salbutamol in asthmatic patients. *Br J Pharmacol*. 1971;43:466P–7P.
- [53]. Bohn D, Kalloghlian A, Jenkins J, Edmonds J, Barker G. Intravenous salbutamol in the treatment of status asthmaticus in children. *Crit Care Med*. 1984;12:892–6.
- [54]. Browne GJ, Trieu L, Van Asperen P. Randomized, double-blind, placebo-controlled trial of intravenous salbutamol and nebulized ipratropium bromide in early management of severe acute asthma in children presenting to an emergency department. *Crit Care Med*. 2002;30:448–53.