

Assessment of quality of life and adverse drug reactions in patients with bronchial asthma

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Abstract

Background: Bronchial asthma is an inflammatory disease of the airway to the lung which makes breathing difficult. According to the Global Asthma Report 2018 asthma is estimated to affect as many as 339 million people worldwide. Asthmatics have a more serious risk of developing ADRs so it is very important to monitor ADR. Since asthma is not a fully curable chronic respiratory disease, it was necessary to assess the quality of life.

Materials and Methods: A total of 84 patients were enrolled in the study as per the inclusion and exclusion criteria. Patients demographics data were collected using data collection form and quality of life were assessed by using St. George’s respiratory questionnaire.

The adverse drug reactions were analysed by using Naranjo causality assessment scale and Hartwig’s scale.

Result: Out of 84 patients, female patients (79.8%) were predominant while comparing to male patients. it is mostly seen in elderly and middle aged patients than younger patients. Most commonly reported ADRs were dryness of mouth and headache and least reported ADRs were tachycardia and vomiting.

Naranjo causality assessment showed that the reported ADRs were probable (42 (%)) and possible (57.1%) ADRs. Hartwig’s severity assessment scale showed that 57.1% of ADRs were mild and 42.9% were moderate. Our study showed impairment in quality of life in the asthma population.

SGRQ questionnaire showed that all components such as symptom, activity, impact and total score is significantly impaired.

Conclusion: The study was conducted to enhance the overall quality of life and can be improved by providing education and awareness about the disease. Careful therapeutic dose monitoring, dose individualisation and appropriate reporting of ADR is necessary to decrease the risk of ADR in patients receiving the treatment.

Keywords: Adverse drug reaction (ADR), Quality of life (QoL), Asthma

Introduction

Bronchial Asthma is an airway illness marked by an enhanced reactivity of the tracheobronchial tree to a variety of stimuli. It is characterised by constriction of the airways, which may be relieved naturally or as a consequence of medication and clinically manifests as dyspnoea, cough, and wheezing paroxysms.^[1]

Asthma affects more than 300 million people globally, nearly a tenth of whom live in India. Asthma is the most prevalent chronic disease among children, with prevalence estimates ranging from 3-38 percent in children to 2-12 percent in adults. According to the Indian Study on Epidemiology of Asthma, Respiratory Symptoms, and Chronic Bronchitis (INSEARCH), which included 85,105 men and 84,470 women from 12 urban and 11 rural sites across India, the prevalence of asthma in India is 2.05 percent among those aged >15 years, with a national burden of 18 million asthmatics.^[2]

WHO defines Quality of Life as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person’s physical health, psychological state, personal beliefs, social

relationships and their relationship to salient features of their environment”.^[3]

Other biological or clinical asthma outcome measures do not capture QOL, which is an essential concept for characterization of patient groups and assessing therapeutic interventions.

Asthma’s impact on QOL is predicted to vary in features and magnitude depending on a variety of patient variables, including age. When compared to mild persistent asthma, moderate to severe asthma has a lower QOL; however, objective measures of disease severity cannot fully assess the personal burden of illness as perceived by the patient; traditional clinical indices for asthma only moderately correlate with how patients feel and live on a daily basis. In asthma, traditional clinical outcomes focus on preventing death and morbidity, while QOL evaluations focus on the patients’ overall well-being.

A component analysis of the connection between patient well-being and asthmatic clinical state revealed that patient well-being cannot be imputed from clinical results and must be assessed and interpreted separately.^[4]

Adverse Drug Reaction (ADR) is defined by WHO, “As a response which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function”.⁵ Anti-asthmatic medications are linked with side effects that can influence compliance and treatment course. As medicine advances and new drugs are produced, there is the possibility for an increase in the number of ADRs. Monitoring adverse drug reactions in asthma patients will be essential in alerting clinicians to the

potential and circumstances of such incidents, therefore saving users from preventable harm. [6]

Clinical Pharmacists can help asthma patients and their physicians achieve and maintain asthma control by providing appropriate for asthma medication information and training, instructing for proper inhalation technique, challenging the patient's understanding of the role of their asthma medications, explaining why inhaled corticosteroids are needed and addressing the patient's concerns about inhaled corticosteroids' possible adverse effects and enabling adherence to controller medication.

These aspects have already been shown to be a significant barrier to good asthma control, since providing a suitable asthma control treatment may not be effective if the patient misuses the medicine. By far, only a few well-designed studies have looked into the impact of pharmacist care on asthma patients. [7]

Therefore it was necessary to assess the quality of life and adverse drug reaction in patients with bronchial asthma. Thus the study was selected with the aim of increasing the quality of asthma patients.

Materials and Methods

Study Site: The General Medicine department, KR Hospital, Mysore.

Study Design: The study is a prospective and observational study.

Study Period: The study was carried out for period of six months from July 1st 2019- December 30th 2019.

Study Criteria

Inclusion Criteria

- In patients with aged above 18 years.
- Patient of both genders.
- Patient admitted as inpatient in medicine department.

- The patients who are willing to participate in this study criteria.

Exclusion Criteria:

- Patient who were not willing for the study.

Ethical approval: Institutional Ethical Clearance (IEC) for this study was obtained from the Institutional Ethical Committee, Mysore Medical College and Research Institute, Mysore with certificate number: IN-KA256160552975821.

Result

The proposed work was carried out in a 1050 bedded multispecialty teaching hospital for a period of 6 month. There were a total of 100 asthma cases in which 84 patients met the inclusion criteria.

Gender Distribution in the Study Population

Among the 84 patients included for the study, 20.2% were males (n=17) and 79.8% were females (n=67). The details of gender distribution are represented in Figure 1. The study conducted by Patil S.S et al; in which the prevalence of asthma was predominant in female patients than male patients. [9]

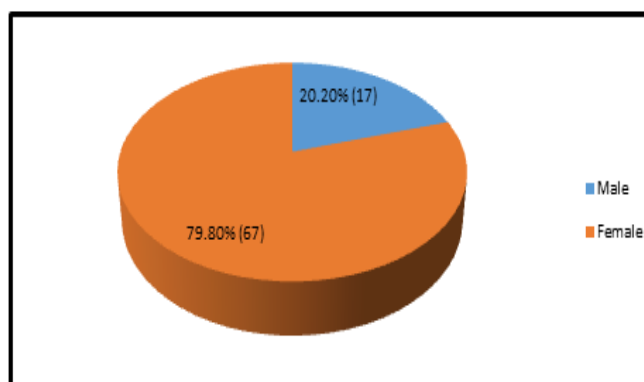


Figure 1: Gender Distribution in the Study Population

Age categorization of the study population

The mean age of the population was found to be 55.8 years (SD+/-10.426). Out of the total study population, maximum of (40.5%) patients belonged to the age group 55-64 years followed by the age groups >64

years (29.8%) and 45-54 years (21.4%). The maximum age of patients in the study population was 68 years and minimum age was 20 years. The details of age categorization are represented in Table 1. This result pointed out that prevalence of asthma is found to be more in elderly and middle aged patients than younger patients. This result was same as study result of Patil S.S et al.^[9]

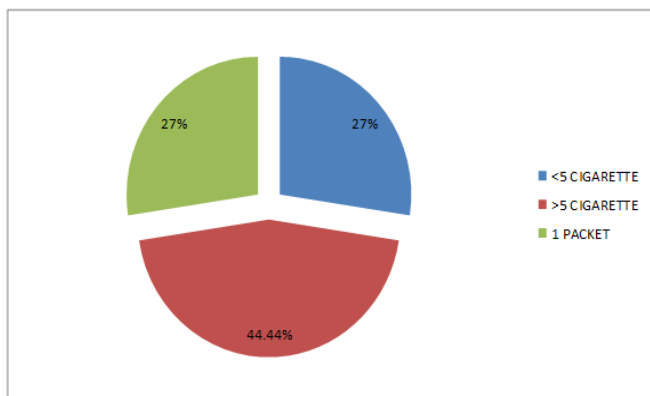
Table 1: Age categorization in the study population

Patient age group(years)	Male	Female
25-34	2 (2.4%)	2 (2.4%)
35-44	1 (1.2%)	2 (2.4%)
45-54	11 (13.1%)	7 (8.3%)
55-64	3 (3.6)	31 (37%)
>64	-	25 (29.8%)

Smoking Status & Cigarette Per Day

Among 84 patients, Only 18 patients (21.4%) were smokers, among these most of the patients use >5 cigarettes per day, that is out of 18 smokers 8 patients use >5 cigarette per day. Details shows in figure 2.

Figure 2: Cigarette per Day



Patients Observed With ADRs

Among 84 patients, 33.3% (n=28) patients were observed with ADRs. Among 28 patients both males and females were shows same frequency, that is 14 (16.6%). 66.7% patients were not observed with

adverse reactions. In this study population, dryness of mouth 9.52% (n=8) is the mostly seen adverse drug reaction and tachycardia & tremor 2.4% (n=2) are the rarely seen adverse reaction. The details are represented in Table 2.

Table 2: Type of adrs in study population

Type of ADRs	Frequency	Percentage (n=84)	Male (16%)	Female (16%)
Vomiting	2	2.4	1	1
Dryness of mouth	8	9.5	4	4
Headache	6	7.1	5	1
Diarrhea	3	3.5	3	
Nausea	3	3.5		3
Tachycardia	2	2.4	1	1
Tremor	4	4.7		4

Age Wise Distribution of ADRs

By analyzing the age distribution, it is seen that the ADR's are mostly seen in elderly and middle aged patients than younger patients. Most of the ADR's are reported in the age group of 45-54 years and 55-64 years as shown in the Table 3.

Table 3: Age Wise Distribution of ADRs

Patient age group	ADRs	No. of cases	Percentage
15-24 years	Vomiting	1	7.1%
	Headache	1	
25-34 years	Dryness of mouth	1	7.1%
	Diarrhea	1	
35=44 years	Diarrhea	1	3.5%
45-54 years	Vomiting	1	39.2%
	Dryness of mouth	3	
	Headache	5	
	Diarrhea	1	
	Tachycardia	1	
55-64 years	Dryness of mouth	4	28.5%
	Tremor	4	

>64 years	Nausea	3	14.2%
	Tachycardia	1	

Type of Adrs According To Medications

In the study population, maximum 39.3% (n=11) ADRs were induced by medication contain Levosalbutamol + ipratropium bromide + budesonide, followed by medication contain montelukast + levocetirizine 32.1% (n=9) and minimum ADRs induced by lorazepam 3.6% (n=1). Total 7 types of ADRs were found. The details are shown in Table 4.

Table 4: type of Adrs according To Medications

Medications	Adrs	Numbers (N=84)	Percentage (N=28)
Acetylcystein	Vomiting	2	7.1
Azithromycin	Diarrhea	3	10.7
Hydrocortisone	Tachycardia	2	7.1
Montelukast + Levocetirizine	Headache	6	21.4
	Dryness Of Mouth	3	10.7
		9	32.1
	Total		
Levosalbutamol +Ipratropium Bromide+ Budesonide	Dryness Of Mouth	4	14.3
		4	14.3
	Tremor	3	10.7
	Nausea	11	39.3
	Total		
Levosalbutamol+ Ipratropium Bromide	Dryness Of Mouth	1	3.6

In a study conducted by Jamali A.N et al, the same result was seen, in which drugs contributing majorly to ADR were found to be Montelukast, salbutamol, ipratropium, salmeterol and hydrocortisone. In our study, the number of ADRs was higher with combination therapy compared to monotherapy. This result is supported by the study conducted by Jamali A.N et al.^[8]

Causality Assessment of ADRs

Out of 28 ADRs, 42.0% (n=12) is probable and 57.1% (n=16) is possible. Dryness of mouth is the most probable one 21.4% (n=6). The details are represented in Table 5.

Table 5: Causality Assessment of ADRs

ADRs	Causality assessment		p-value
	Probable	Possible	
Vomiting	1 (3.5%)	1 (3.5%)	0.118
Dryness of mouth	2 (7.1%)	6 (21.6%)	
Headache	5 (17.9%)	1 (3.5%)	
diarrhea	1 (3.5%)	2 (7.1%)	
Tremor	2 (7.1%)	2 (7.1%)	
Nausea	3 (10.7%)	0	
Tachycardia	2 (7.1%)	0	
Total	16 (57.1%)	12 (42.9%)	

Our study results which were observed by Naranjo Causality assessment scale shows that 42.9% were “probable” and 57.1% were “possible” ADRs. A study conducted by Jamali A.N et al, also showed same result in which 60% of the events were found to be possible and 40% as the probable ADRs. Another study by Khan A et al, also showed similar results in which, 55% of ADRs were categorized to probable and 42.5% as possible ADRs.^[8,10]

Severity Assessment of ADRs

In the study population, 28 patients show ADRs (SD+/- 0.504). Out of 28, 12 (42.9%) ADRs were moderate, 16 (57.1%) ADRs were mild. The detailed information are represented in Table 6.

Table 6: Severity Assessment of ADRs

ADRs	Severity		p-value
	Mild	Moderate	
Vomiting	1 (3.5%)	1 (3.5%)	0.118
Dryness of mouth	2 (7.1%)	6 (21.6%)	
Headache	5 (17.9%)	1 (3.5%)	
diarrhea	1 (3.5%)	2 (7.1%)	
Tremor	2 (7.1%)	2 (7.1%)	
Nausea	3 (10.7%)	0	
Tachycardia	2 (7.1%)	0	
Total	16 (57.1%)	12 (42.9%)	

Hartwig’s severity assessment scale shows 57.1% of the total ADRs are mild and 42.9% are moderate. This shows that most of the reported reactions are mild in severity. Similar result is also seen in the study conducted by Khan A et al, in which 51.25% of the suspected reactions were mild and 27.5% were moderate.^[10]

Quality of life

How you describe your current health

Among the study population, 39.3%% patients health are fair (n=33) followed by 29.8% good health (n=25) and the least is 6% very poor (n=5). The details are described in the figure 3.

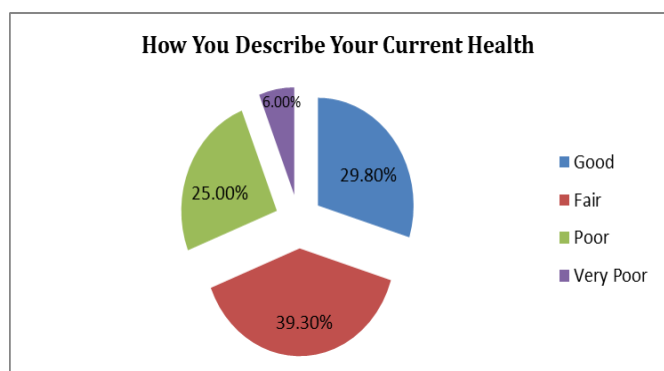


Figure 3: how you describe your current health

According to many studies, Asthma is one of the major public health threats in India. The patients with Asthma are facing many health problems and are challenged with restricted physical activities and reduced HRQOL.

Poor QOL is mainly due to dyspnoea and comorbidities. In our study the mostly seen symptom is dyspnoea.

Quality of life scores of asthma patients

The mean symptom, activity, impact and total score observed were 23.63, 38.35, 34.36 and 34.35 respectively. The scores showed significant impairment in all three domain scores, i.e., symptoms, activity and impact when compared with reference values. In our study the activity component is most affected while symptom component is least affected. Similar result is seen in another study conducted by Sabin T et al, in which activity component is highly impaired and symptom component is less impaired.^[11]

Table 7: Quality of life with their scores

Scores	Mean	St. Deviation
Symptom Score	23.63	5.831
Activity score	38.35	21.350
Impact Score	34.36	16.509
Total Score	34.35	15.098

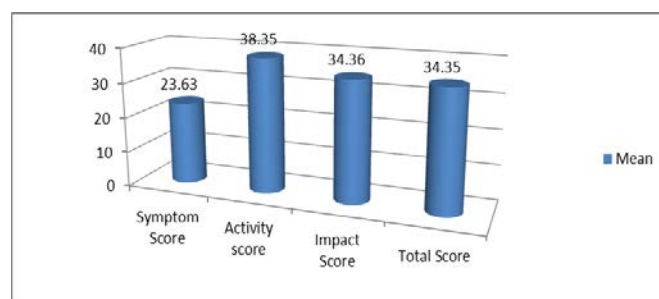


Figure 4: Quality of life with their scores

QOL score comparison

In the study population, among 84 patients QOL scores like symptom, activity, impact and total scores are compared with gender distribution, age group,

education status and patients observed with adverse drug reactions.

(a) QOL score according to gender distribution

It is found that the mean of symptom, activity, impact and total score of the male patients in the study population were 21.0, 48.12, 47.12 and 45.12

respectively. The mean of symptom, activity, impact and total score of the female patients in the study population were 23.63, 55.35, 67.75 and 57.25 respectively. This data indicates that the activity component and impact component is significantly impaired in male and female patients.

Scores	Male			Female		
	Frequency	Mean	St. Deviation	Frequency	Mean	St. Deviation
Symptom Score	17	21	0.00	67	23.63	5.831
Activity Score	17	48.12	11.056	67	55.35	9.381
Impact Score	17	47.12	11.056	67	67.75	9.381
Total Score	17	45.12	11.056	67	57.25	9.381

Table 8: QOL score according to gender distribution

(b) Quality of life according to age group

In our study, in age group 15-24, the most affected component is symptom and impact component. In the age group 25-34, all the three components is equally affected. In the age group 35-44, impact component is

most affected and symptom component is least affected. In the age group 45-54, activity and impact component is equally affected. In the age group 55-64, impact component is most affected. In the age group >64, activity and impact score is most affected.

Age groups	Symptom Score		Activity Score		Impact Score		Total Score	
	Frequency	Mean	Frequency	Mean	Frequency	Mean	Frequency	Mean
15-24	2	21.00	2	11.00	2	21.00	2	21.00
25-34	2	32.00	2	32.00	2	32.00	2	32.00
35-44	3	32.00	3	36.00	3	43.00	3	36.00
45-54	18	28.61	18	48.61	18	48.00	18	58.21
55-64	34	27.50	34	57.50	34	57.51	34	59.55
>64	25	32.03	25	65.72	25	67.50	25	68.72

Table 9: Quality of Life According to age group

(c) Quality of life according to education of the patient

In our study, activity and impact component is equally affected in uneducated and primary educated patients.

In patients with secondary education, the most effected components are symptom and activity component.

Education of Patient	Symptom Score		Activity Score		Impact Score		Total Score	
	Frequency	Mean	Frequency	Mean	Frequency	Mean	Frequency	Mean
None At All	56	32.30	56	59.23	56	58.05	56	60.01

Primary	23	29.85	23	54.09	23	59.72	23	59.34
Secondary	5	25.20	5	25.25	5	24.93	5	25.00

Table 10: Quality of life according to education of the patient

(d)QOL Scores versus Cigarette/Day In patients taking < 5 cigarettes and >5 cigarettes and 1 packet, we found that the impact component is most affected.

Cigarettes/Day	Symptom Score		Activity Score		Impact Score		Total Score	
	Frequency	Mean	Frequency	Mean	Frequency	Mean	Frequency	Mean
<5 Cigarette	5	24.40	5	54.50	5	56.00	5	53.95
>5 Cigarette	8	29.88	8	49.88	8	50.25	8	49.88
1 Packet	5	29.60	5	49.60	5	48.73	5	48.89

Table 11: QOL scores versus cigarette/day

(e)QOL Scores versus patient observed with ADR’S.

In both patients with ADR and without ADR, the most affected component is impact component and least affected component is symptom component.

Scores	Patient Observed With ADR’s	Frequency	Mean
Symptom score	Yes	28	28.54
	No	56	21.16
Activity score	Yes	28	58.11
	No	56	51.14
Impact score	Yes	28	60.25
	No	56	55.75
Total score	Yes	28	48.96
	No	56	42.68

Table 12: QOL Scores versus Patient Observed With ADRs

Conclusion

Asthma is a leading respiratory disease affecting both the length and quality of life. The prevalence of asthma has been increased since the early 1980s for all aged, sex and racial groups. In our study female patients were more in number when compared with males.

Prevalence of asthma is more seen in elderly and middle aged people than younger ones. ADRs are associated with considerable morbidity, mortality and high medical cost. Polypharmacy is common in patients with Asthma. So they are at high risk of developing ADR. Careful therapeutic monitoring and dose individualisation is necessary to minimize the incidence of ADR. In our study out of 84 patients, 28 patients are observed with ADR, in which 14 are male patients and rest are female. The most common reported ADRs were dryness of mouth, headache and tremor. Tachycardia and vomiting were also reported but in less frequency. Levosalbutamol+ ipratropium bromide+ budesonide (Duolin) and Montelukast+ levocetirizine (Montek LC) are the major drugs contributing to ADR. All the reported ADRs were categorized as mild and moderate. Naranjo causality assessment provided all the reported ADRs come under probable and possible. In our study, QOL was impaired in patients with Asthma. The activity component is most affected and symptom component is least affected among the population. Increasing age, illiteracy, increase in the number of

cigarette consumption and presence of co morbidity led to decrease QOL in Asthma patients. We need to increase our focus on more treatable aspects of QOL, which might lead to improved care of Asthma patients. The clinical pharmacists have a major role in improving patient knowledge and thereby significantly improve the quality of life.

Abbreviations

ACQ - Asthma Control Questionnaire

ADE – Adverse Drug Events

ADR - Adverse Drug Reaction

AQLQ - Asthma Quality of Life Questionnaire

HRQoL- Health Related Quality of Life

INSEARCH - Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis

QOL - Quality of life

SGRQ- St. George's respiratory questionnaire

WHO - World health organisation

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