Original Article

Health-related quality of life assessment using St. George's respiratory questionnaire in asthmatics on inhaled corticosteroids

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ABSTRACT

Context: Chronic diseases like asthma have significant effects on patients' health-related quality of life (HRQoL). HRQoL measures additional indices as compared to objective measurements like spirometry. **Aims:** To assess and compare disease-specific quality of life in asthma patients using St. George's Respiratory Questionnaire (SGRQ) receiving fluticasone, beclomethasone, and budesonide (BUD). **Settings and Design:** A prospective, open label, randomized, parallel group study conducted at a tertiary care teaching hospital in South India. **Materials and Methods:** A 6-month follow-up of 277 patients with mild, moderate, and severe persistent asthma was randomized to receive fluticasone propionate (FP), BUD, or beclomethasone dipropionate (BDP) in equipotent doses according to their global initiative on asthma (GINA) severity. Statistical analysis used: Data analyzed using SPSS version: 13.0. General linear-repeated measures using the post-hoc bonferroni method assessed significance between treatment groups. **Results:** Significant decrease ($P < 0.05$) in each SGRQ domains and total scores as well as improvement in FEV_1 ($P < 0.05$) was observed in all study subjects. A significant early response ($P < 0.05$) was noted after 15 days treatment in patients receiving FP with respect to SGRQ (activity, impact and total) scores and dyspnea indices, but not FEV_1. This improvement with FP was due to its greater effect in patients with moderate and severe persistent asthma. No difference was noted subsequently in all outcome measures studied until 6 months. **Conclusions:** There was evidence for an early QoL improvement to FP as compared to BUD or BDP in moderate and severe persistent asthma. Subsequently, the three ICS showed similar improvements in lung functions and dyspnea indices throughout the study.

KEY WORDS: Asthma, health-related quality of life, inhaled corticosteroids

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INTRODUCTION

Health-related quality of life (HRQoL) assessment in asthma is a more responsive outcome measure than spirometry.[1] HRQoL measurement facilitates the evaluation of efficacy of medical interventions and also detection of groups at risk for psychological or behavioral problems.[2] QoL unique to each individual is influenced by the perception of disease.[3] Current clinical guidelines recommend inhaled corticosteroids (ICS) as the mainstay of therapy in chronic asthma.[4]

Beclomethasone dipropionate (BDP), budesonide (BUD), and fluticasone propionate (FP) are the most commonly used ICS in the management of asthma. Clinically, BDP and BUD are considered to be equivalent in therapeutic efficacy and tolerability on a microgram to microgram basis.[5,6] FP used at half the dose of BUD and BDP have shown similar efficacy with reduced systemic side effects.[7]

Disease-specific health status measures are distinguished by its higher responsiveness than the generic measures and are widely used in clinical trials.[8] St. George's Respiratory Questionnaire (SGRQ) was designed to measure HRQoL both in asthma and COPD patients,[9] but no studies

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measuring the improvement in HRQoL in asthmatics using the SGRQ comparing different ICS with long acting beta agonists (LABA) is reported.

Dyspnea is another subjective clinical term to express the symptom of breathlessness or shortness of breath experienced by asthmatics. Morbidity associated with dyspnea is unpredictable ranging from a minor irritation to functional incapacity. Presently, dyspnea is used as an important outcome measure in the intervention studies for chronic lung diseases.[10] Baseline and transition dyspnea indices are useful measures of dyspnea as a symptom and are routinely used in COPD studies,[11,12] but not in asthma. The present study compared the QoL using the SGRQ in asthmatics receiving FP, BDP, or BUD in equipotent doses along with a LABA, Salmeterol.

MATERIALS AND METHODS

The study was conducted at J.S.S Medical College Hospital, a tertiary care teaching hospital in South India, during the period January 2002 to June 2005. It was a prospective, open labeled, randomized, parallel group study of 6 months' duration. Patients enrolled were steroid naive persistent asthmatics of varying severity above 12 years of age, and were directly randomized (computer assisted random sampling) to the study without run in period.

American Thoracic Society (ATS) guidelines[13] were followed for the spirometric procedure. The patients with forced expiratory volume in 1 s (FEV_1) less than 80% with post bronchodilator FEV_1 improvement ≥12% and 200 ml were included. Patients were excluded if they used oral steroids in the past 6 months, suffering from any significant co-morbidities, acute infective exacerbations in the past 4 weeks and were pregnant or lactating. Ethics approval for the study protocol was obtained from Institutional Ethics Committee of the study site, and all patients signed a written informed consent before entering into the study.

Enrolled patients randomly received equipotent dosages of the three ICS FP-125 μg or BDP-200 μg or BUD-200 μg through a pressurized metered dose inhaler (pMDI) device without a spacer, according to their disease severity based

Table 1: Demographic characteristic at baseline

Demography	Budesonide	Fluticasone	Beclomethasone	Total (%), (± SD)
No. of patients enrolled	75	75	75	225
Drop outs	13	12	13	38 (16.88)
Study completers*	62	63	62	187
Gender*				
Male	28	30	28	86 (46.0)
Female	34	33	34	101 (54.0)
Duration in years (mean ± SD)**	5.51 ± 7.11	6.85 ± 7.77	7.34 ± 8.7	6.51 ± 7.88
Age ** (mean years ± SD)	37.75 ± 30.34	35.12 ± 14.32	34.96 ± 14.75	35.81 ± 14.2
Educational status*				
Illiterate	15	7	16	38 (20.3)
≤ 5th Std	3	4	5	12 (6.4)
6th to 10th	24	31	24	79 (42.2)
≥ PUC	20	21	17	58 (31.0)
Family history*				
Positive	28	28	27	83 (44.4)
Negative	34	35	35	104 (55.6)
Smoking history*				
Past smokers	6	5	2	13 (7.0)
Non-smokers	56	58	60	174 (93.0)
GINA severity grading*				
GINA-2 *Mild persistent*	11	14	12	37 (19.8)
GINA-3 *Moderate persistent*	36	33	32	101 (54.01)
GINA-4 *Severe persistent*	15	16	18	49 (26.2)
Lung function** (mean ± SD)				
FVC	1.50 ± 0.68	1.57 ± 0.63	1.53 ± 0.63	1.54 ± 0.62
FEV_1	1.28 ± 0.58	1.31 ± 0.52	1.26 ± 0.51	1.29 ± 0.55
Quality of life *SGRQ domains* (mean ± SD)**				
Symptom	64.28 ± 14.46	63.25 ± 14.86	64.77 ± 14.74	64.10 ± 14.63
Activity	68.85 ± 20.23	71.84 ± 21.93	74.54 ± 16.23	71.78 ± 19.63
Impact	66.90 ± 19.31	64.43 ± 18.70	70.48 ± 16.75	67.28 ± 18.35
Total	67.07 ± 16.49	66.55 ± 16.79	70.80 ± 13.21	68.15±15.60
Baseline dyspnea index#				
Functional impairment	2.19 ± 0.60	2.08 ± 0.58	2.08 ± 0.66	2.12 ± 0.61
Magnitude of task	2.15 ± 0.70	2.16 ± 0.54	2.03 ± 0.72	2.11 ± 0.66
Magnitude of effort	2.19 ± 0.65	2.13 ± 0.55	2.06 ± 0.62	2.13 ± 0.61
Focal scores	2.17 ±0.59	2.12 ± 0.51	2.05 ± 0.62	2.11 ± 0.57

PUC: Pre University College, GINA: Global initiative on asthma, FEV_1: Forced expiratory volume in 1s, SD: Standard deviation, *P value > 0.05 not significant by the chi-square test, ** P value > 0.05 not significant by analysis of variance # P value >0.05 not significant by the Kruskal-Wallis test

on GINA guidelines.[14] The patients were checked for the pMDI techniques at baseline and at every follow-up until the end of the study because they were not allowed to use spacers to attain uniformity among all patients. Patients who never used an MDI previously were initially trained for the standard techniques of inhalation.

A checklist was developed containing ten steps, based on the standard procedure involved, in order to assess the proper use of pMDIs without spacer. Patients were assessed individually for the appropriate use of pMDI. Difficult steps were identified for each patient and were educated. Training was given using placebo inhaler after carefully observing the performance of each step by the patient. The inhalational techniques were checked at subsequent follow-ups to reinforce the appropriateness.

Clinical evaluation, SGRQ, spirometry, and BDI-TDI[15] were assessed at baseline and during follow-up visits at 15, 30, 45, 60, 90, 120, and 180 days. Long acting β_2 agonist-salmeterol 100 mcg/day pMDI in two divided doses was used in all patients (GINA II, III, and IV) to attain uniformity in treatment. Salbutamol 200 mcg pMDI was used as a rescue medication throughout the study.

Statistics

Data were analyzed by using Statistical Program for Social Science (SPSS) version: 13.0. The expected mean difference between equipotent BDP/BUD and FP was 5%. To show a significant difference between the three treatment groups, 225 patients (75 in each group) were included (power 80%, expecting 20% dropout) with an alpha equal to 5% for a two tailed test.

Descriptive statistics for improvement in QoL scores, lung functions, and dyspnea are presented as mean and 95% confidence interval (CI). To assess the similarities between the groups at baseline, Chi-square, Kruskal-Wallis, and ANOVA (Analysis of Variance) were used. General linear-repeated measures using post-hoc bonferroni method assessed significance between treatment groups during the study. The significant improvements in treatment groups were assessed by one-way ANOVA using post hoc-bonferroni that compared means of SGRQ scores and lung functions during individual follow-ups. The dyspnea scales were assessed using non-parametric tests like Kruskal-Wallis and Mann-Whitney U tests.

RESULTS

Study population

A total of 225 patients randomized for an equal distribution of 75 patients in each group. Thirty-eight patients dropped out at various stages of the study, while 187 patients completed the 6-month study period. Reasons for drop out included long distance to travel (n = 11), worsening of asthma symptoms (n = 6), irregular follow-up visits (n = 8), and improved symptoms (n = 13).

The mean age of patients who participated in the study was 35.8 years (±14.2), with nearly equal gender distribution [male (46%): female (54%)] and most were literates (79.7%) and non-smokers (93%). Demographic data, spirometry, QoL scores and dyspnea scales of the three groups [Table 1] were well matched at baseline ($P > 0.05$). A majority of patients had moderate persistent asthma (54.5%) and moderate impairment of BDI.

Spirometry

No significant difference in FVC and FEV_1 ($P > 0.05$) was demonstrated between the three groups throughout the study. A significant improvement ($P < 0.05$) from baseline was demonstrable at the 15th day in both FVC and FEV_1 [Figure 1a], but not subsequently in all patients. Serial evaluation of FVC and FEV_1 revealed that major (80%) improvement was obtained within first 15 days. Improvement in lung functions was comparable ($P > 0.05$) in patients with different severity of the disease throughout the study [Figures 1b-d].

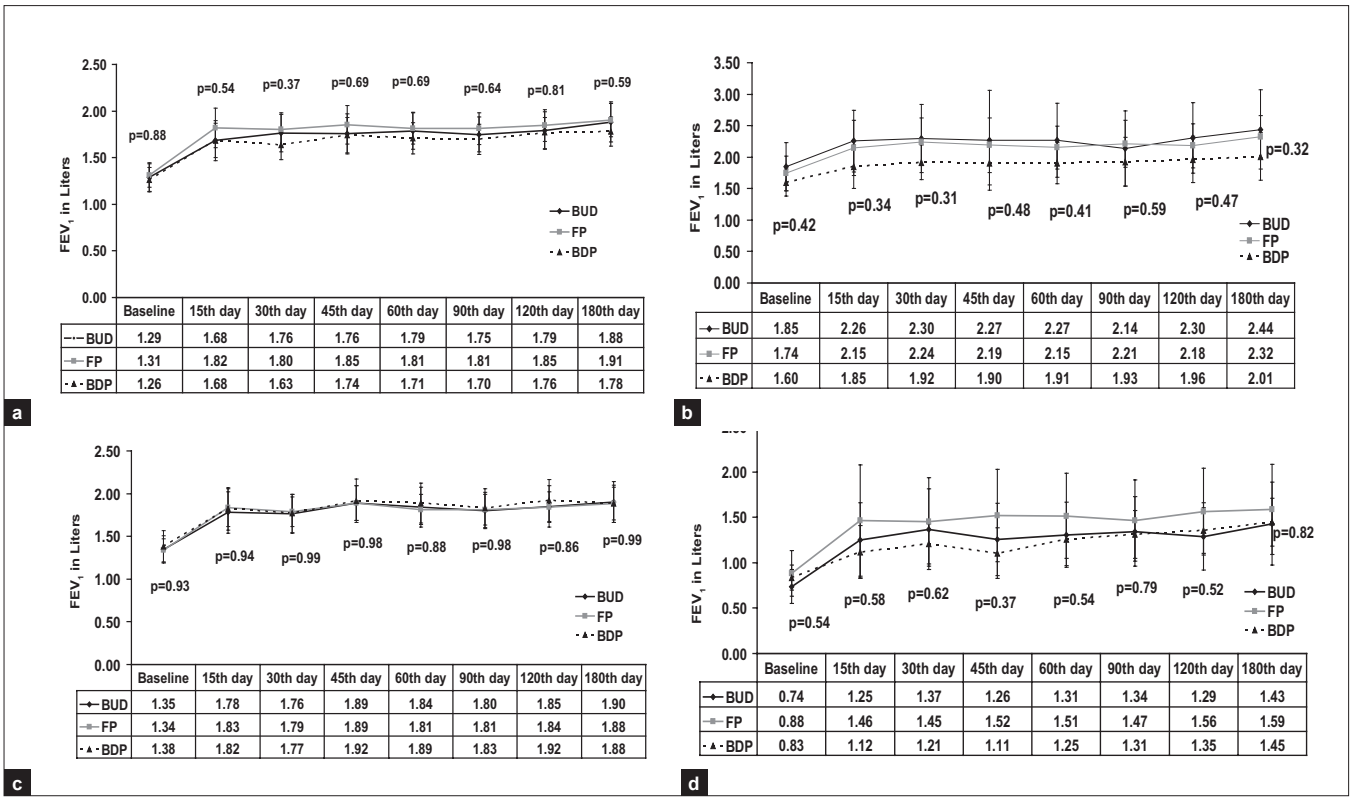
No significant difference was observed ($P > 0.05$) in absolute FVC values comparing FP versus BUD (0.027, 95% CI, –0.33, 0.39), FP versus BDP (0.046, 95% CI, –0.3, 0.4) and BUD versus BDP (0.074, 95% CI, –0.28, 0.43). Similarly, absolute FEV_1 values were also not significantly different between the groups ($P > 0.05$), FP versus BUD (0.022, 95% CI, –0.33, 0.29), FP versus BDP (0.124, 95% CI, –0.18, 0.43) and BUD versus BDP (0.102, 95% CI, –0.21, 0.41).

There was no significant difference ($P > 0.05$) in change in FVC from baseline comparing FP versus BUD (91.93, 95% CI, –202.9, 386.2), FP versus BDP (9.52, 95% CI, –282.6, 301.7) and BUD versus BDP (101.15, 95% CI, –193.4, 395.7). Similarly, changes in FEV_1 from baseline values were also not significant between the groups ($P > 0.05$), FP versus BUD (2.77, 95% CI, –233.5, 239), FP versus BDP (75.7, 95% CI, –158.7, 310), and BUD versus BDP (78.4, 95% CI, –157.9, 314.7).

Quality of Life Improvement

A rapid improvement in all the domains of QoL was noted in study subjects [Figures 2a-d]. Nearly 69% of the total improvement was observed after 15 days of treatment. All domains of the SGRQ continued to improve after 15 days in subsequent follow-ups till 6 months at a slower rate. A significant improvement within groups could be demonstrated for all the domains only at the 15th day ($P < 0.05$), but not subsequently ($P > 0.05$).

Inter-group comparisons revealed a significant ($P < 0.05$) response to FP in all the domains of the SGRQ at 15th day. Later, the improvement in the symptom domain between the three ICS was comparable till the end of the study [Figure 2b]. The significant response in favor of FP persisted in the activity [Figure 2b], impact [Figure 2c] and total scores [Figure 2d] of the SGRQ until 2 months. Further improvements were comparable between the three



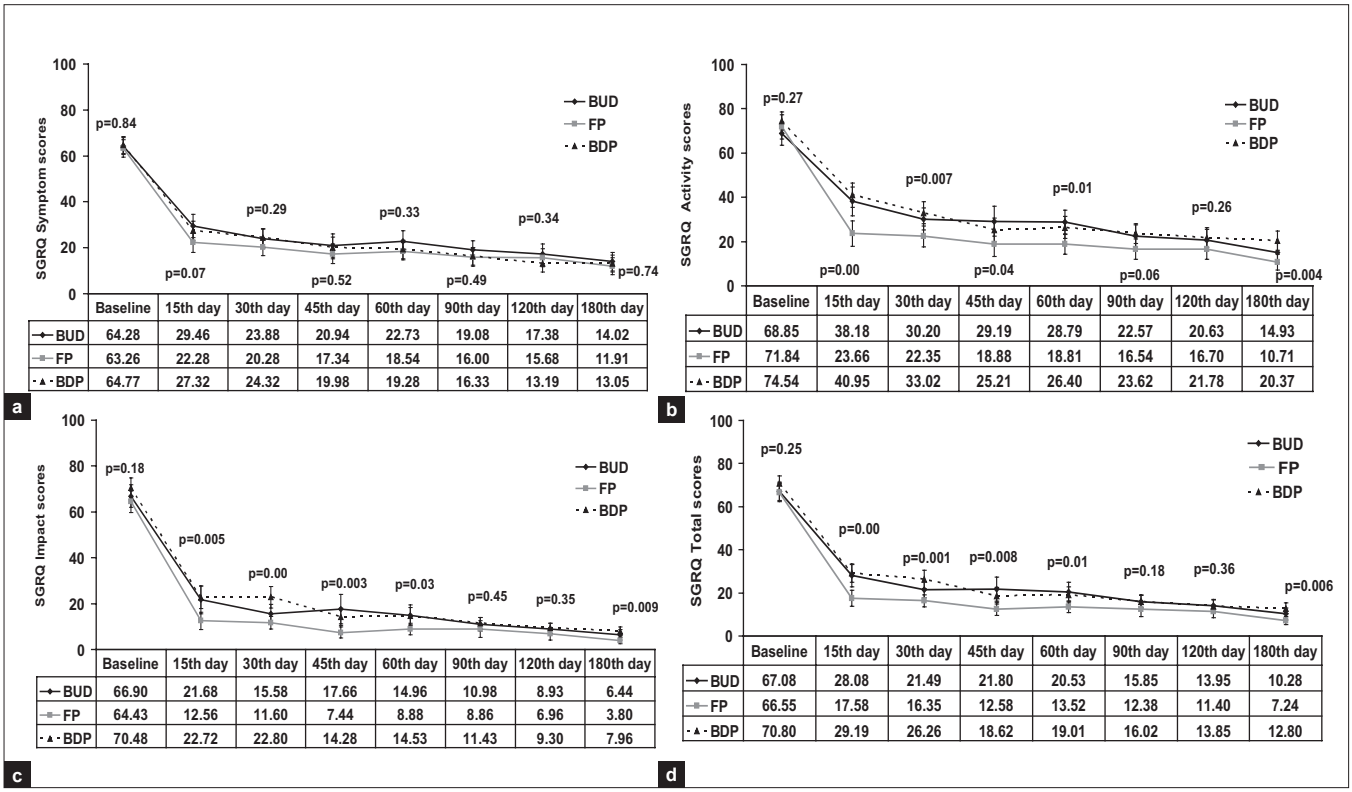
a	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	1.29	1.68	1.76	1.76	1.79	1.75	1.79	1.88
FP	1.31	1.82	1.80	1.85	1.81	1.81	1.85	1.91
BDP	1.26	1.68	1.63	1.74	1.71	1.70	1.76	1.78

b	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	1.85	2.26	2.30	2.27	2.27	2.14	2.30	2.44
FP	1.74	2.15	2.24	2.19	2.15	2.21	2.18	2.32
BDP	1.60	1.85	1.92	1.90	1.91	1.93	1.96	2.01

c	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	1.35	1.78	1.76	1.89	1.84	1.80	1.85	1.90
FP	1.34	1.83	1.79	1.89	1.81	1.81	1.84	1.88
BDP	1.38	1.82	1.77	1.92	1.89	1.83	1.92	1.88

d	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	0.74	1.25	1.37	1.26	1.31	1.34	1.29	1.43
FP	0.88	1.46	1.45	1.52	1.51	1.47	1.56	1.59
BDP	0.83	1.12	1.21	1.11	1.25	1.31	1.35	1.45

Figure 1: Improvement in absolute lung functions (FEV_1) by all asthma severity (a) Combined asthma severity, (b) Mild persistent asthma, (c) Moderate persistent asthma, (d) Severe persistent asthma $P > 0.05$ not significant by ANOVA. Values represented as mean and 95% confidence interval (Y error bars). FP: Fluticasone propionate, BDP: Beclomethasone dipropionate, BUD: Budesonide. FEV_1: Forced expiratory volume in 1 s.



a	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	64.28	29.46	23.88	20.94	22.73	19.08	17.38	14.02
FP	63.26	22.28	20.28	17.34	18.54	16.00	15.68	11.91
BDP	64.77	27.32	24.32	19.98	19.28	16.33	13.19	13.05

b	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	68.85	38.18	30.20	29.19	28.79	22.57	20.63	14.93
FP	71.84	23.66	22.35	18.88	18.81	16.54	16.70	10.71
BDP	74.54	40.95	33.02	25.21	26.40	23.62	21.78	20.37

c	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	66.90	21.68	15.58	17.66	14.96	10.98	8.93	6.44
FP	64.43	12.56	11.60	7.44	8.88	8.86	6.96	3.80
BDP	70.48	22.72	22.80	14.28	14.53	11.43	9.30	7.96

d	Baseline	15th day	30th day	45th day	60th day	90th day	120th day	180th day
BUD	67.08	28.08	21.49	21.80	20.53	15.85	13.95	10.28
FP	66.55	17.58	16.35	12.58	13.52	12.38	11.40	7.24
BDP	70.80	29.19	26.26	18.62	19.01	16.02	13.85	12.80

Figure 2: Improvement in St. George's respiratory questionnaire domains (a) Symptom domain, (b) Activity domain, (c) Impact domain, (d) Total. $P > 0.05$ not significant by ANOVA. Values represented as mean and 95% confidence interval (Y error bars). FP: Fluticasone propionate, BDP: Beclomethasone dipropionate, BUD: budesonide

groups except at the end of the study.

On subgroup analysis as mild, moderate, and severe persistent asthma (GINA), all the domains of the SGRQ were well matched at baseline between the three groups. The improvements in symptom were comparable between the three ICS [Figures 3-5]. A significant ($P < 0.05$) improvement in activity and total scores were observed in favor of fluticasone in moderate and severe persistent asthma, but not in mild persistent asthma. The impact scores in favor of fluticasone were noted in majority of follow-ups only in moderate persistent asthma. Within the group, analysis revealed a significant improvement ($P < 0.05$) in all the domains of the SGRQ only on the 15th day in all the three ICS in mild, moderate, and severe persistent asthma, but not subsequently.

Patients experienced acute exacerbations during treatment irrespective of ICS groups and were classified as infective and non-infective. The non-infective exacerbations were due to climatic changes, unavoidable/unexpected exposure to triggers, and increased physical activities. The least number of exacerbations were noted in the FP group 34 (16 infective and 18 non-infective), followed by BUD 44 (20 infective and 24 non infective) and BDP 48 (21 infective and 27 non infective). BDP-treated patients experienced a majority of exacerbations.

Dyspnea

BDI items showed a higher reliability coefficient ($\alpha = 0.91$) providing evidence to measure dyspnea in asthma. The BDI focal scores correlated well with FEV_1 ($r = 0.45$, $P < 0.01$), overall QoL ($r = -0.38$, $P < 0.01$), symptom domain ($r = -0.26$, $P < 0.01$), and activity domain of the SGRQ ($r = –0.28$, $P < 0.01$).

Transition dyspnea indices [Figure 6] showed a clinically and statistically significant improvement in favor of FP on the 15th and 30th day, but not subsequently. The clinically significant change (> 1 unit) was noted by the 15th day in patients receiving FP and was noted only at the 45th day in patients receiving BUD and BDP. On subgroup analysis, the results were comparable between the three ICS in mild persistent asthma and a clinical and a statistical difference between the groups in favor of FP were observed in the 15th and 30th day in moderate persistent and only on 15th day in severe persistent asthma.

DISCUSSION

The Cochrane review to assess the safety and efficacy of FP and BDP or BUD in chronic asthma highlights the paucity of studies assessing the health-related status of asthmatics using disease-specific QoL instruments. All patients were steroid naïve and parallel group design further ensured that

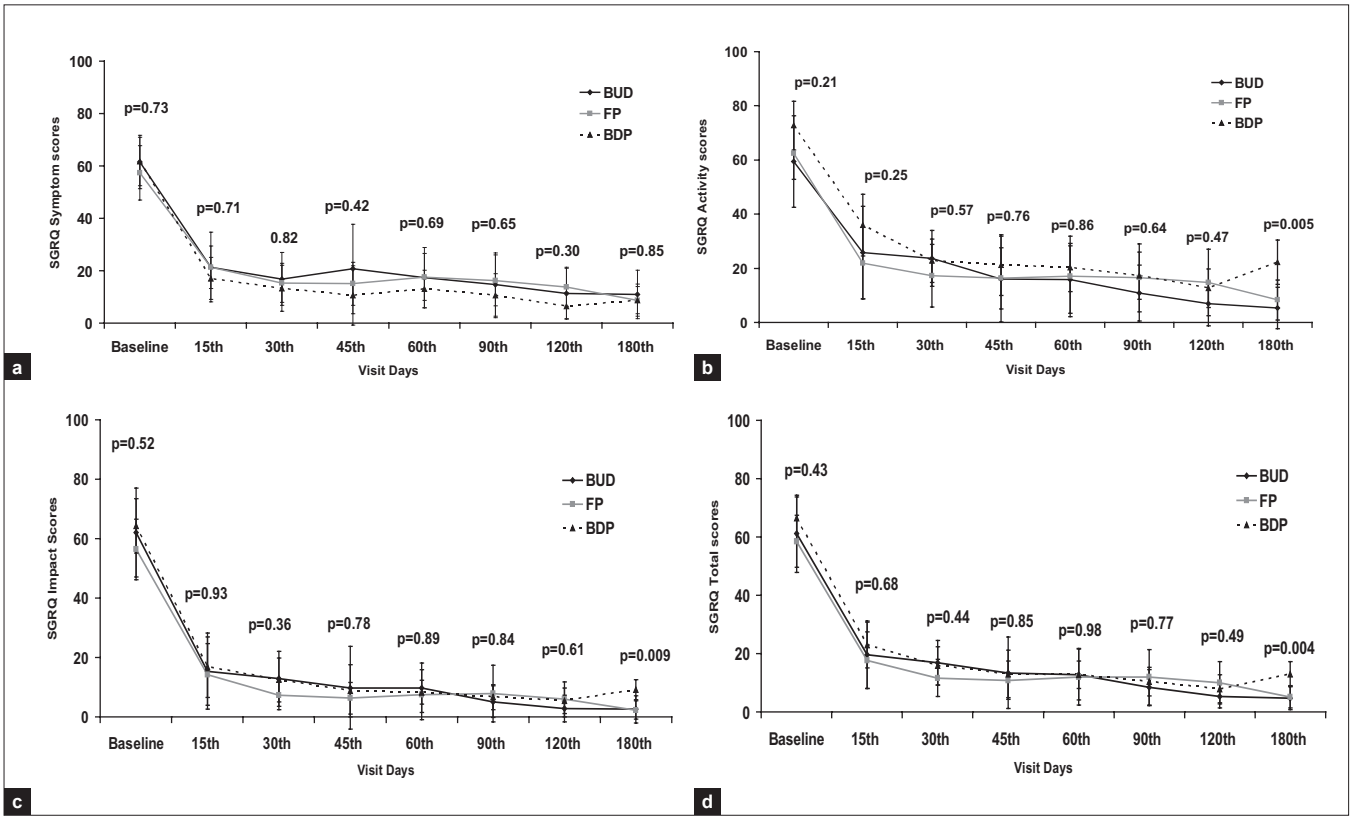


Figure 3: Improvement in St. George's Respiratory questionnaire domains of GINA-2 patients (a) Symptom domain, (b) Activity domain, (c) Impact domain, (d) Total $P > 0.05$ not significant by ANOVA. Values represented as mean and 95% confidence interval (Y error bars). FP: Fluticasone propionate, BDP: Beclomethasone dipropionate, BUD: Budesonide

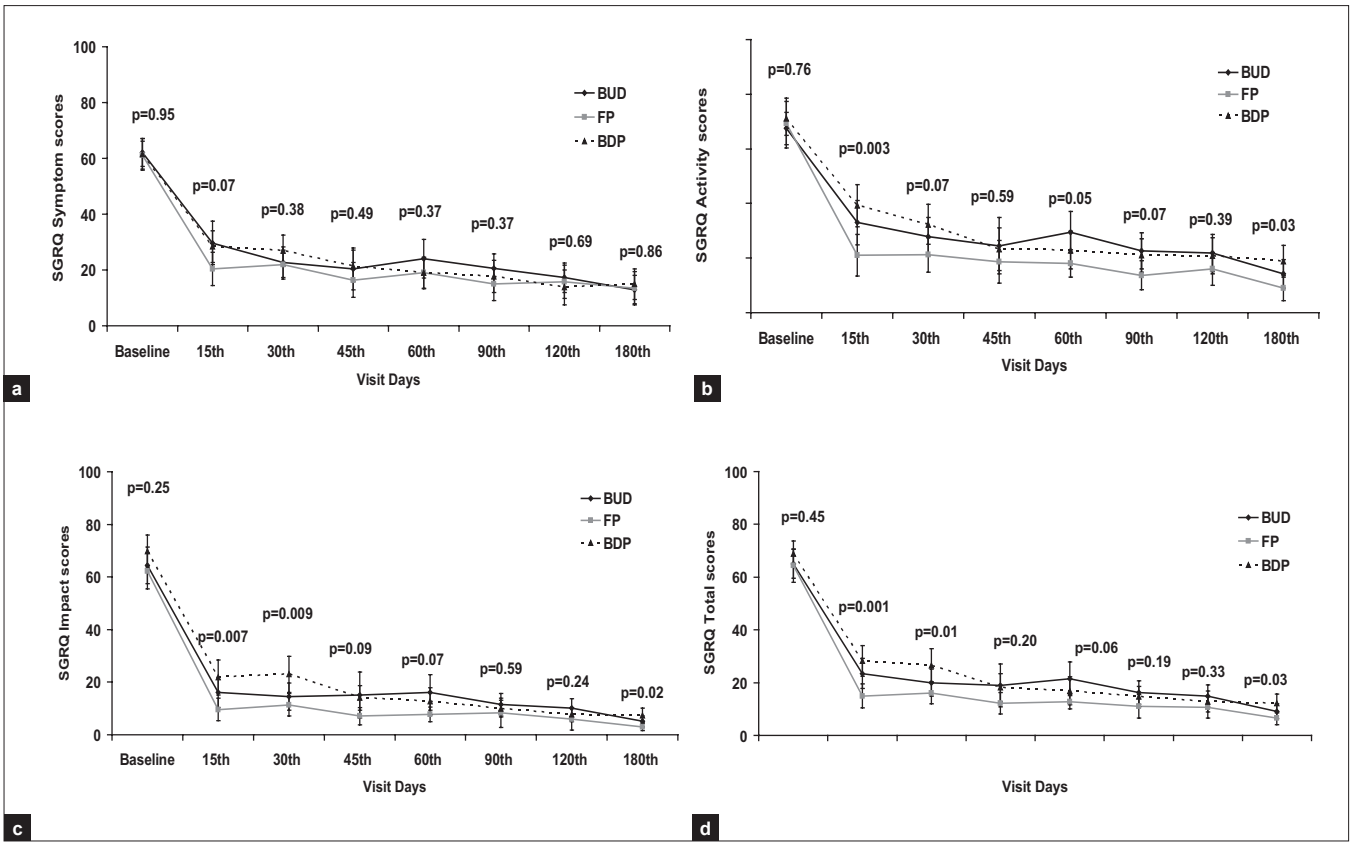


Figure 4: Improvement in St. George's respiratory questionnaire domains of GINA-3 patients (a) Symptom domain, (b) Activity domain, (c) Impact domain, (d) Total. *P* > 0.05 not significant by ANOVA. Values represented as mean and 95% confidence interval (Y error bars), FP: Fluticasone propionate, BDP: Beclomethasone dipropionate, BUD: Budesonide.

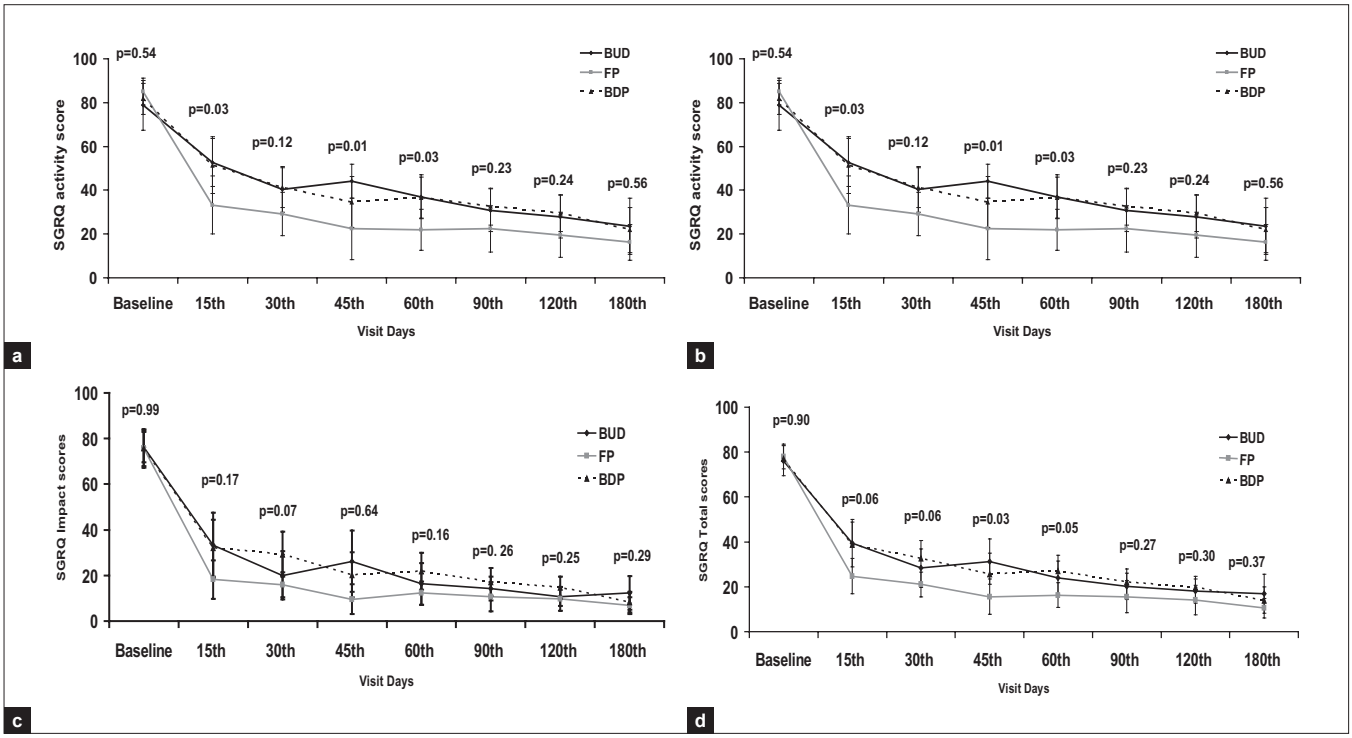


Figure 5: Improvement in St. George's respiratory questionnaire domains (a) Symptom domain, (b) Activity domain, (c) Impact domain, (d) Total. *P* > 0.05 not significant by ANOVA. Values represented as mean and 95% confidence interval (Y error bars), FP: Futicasone propionate, BDP: Beclomethasone dipropionate, BUD: Budesonide

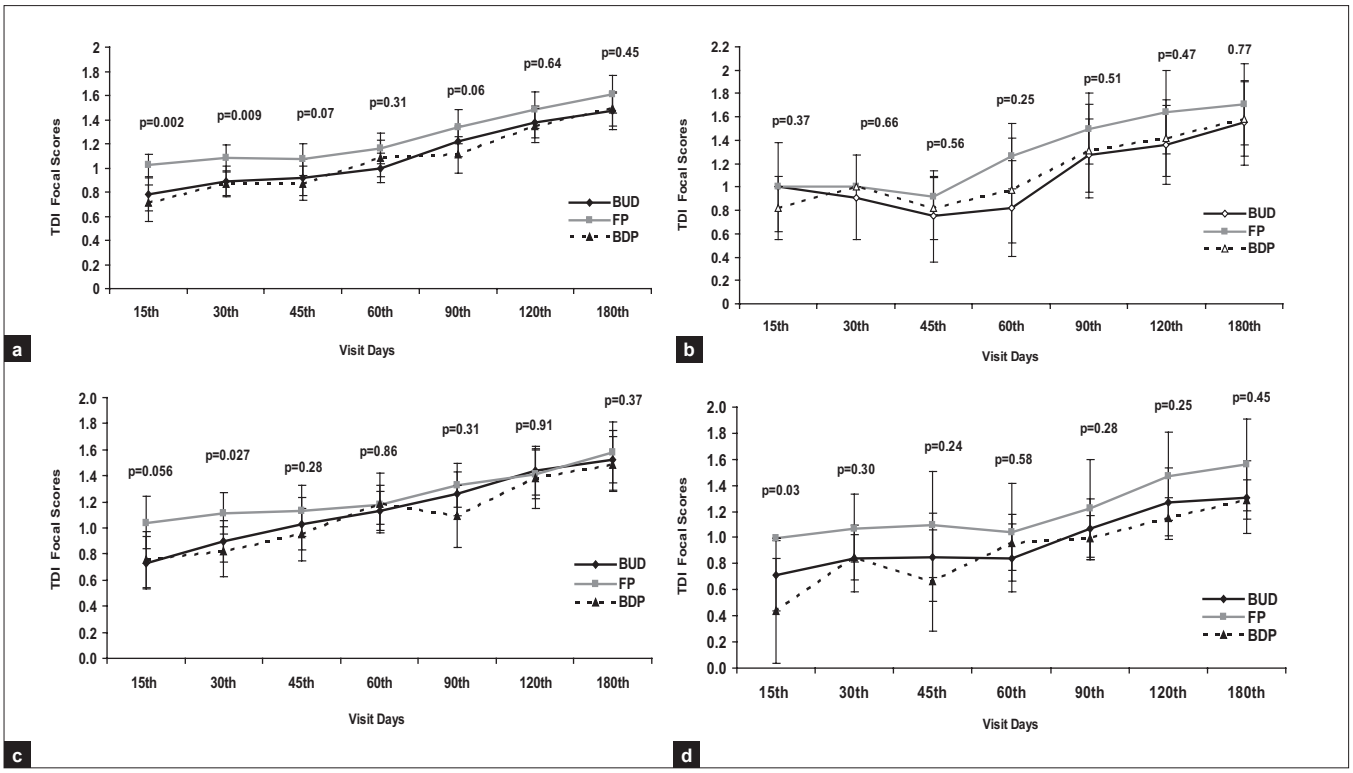


Figure 6: Improvement in transition dyspnea index by all GINA severity (a) Combined asthma severity (b) Mild persistent asthma (c) Moderate persistent asthma (d) Severe persistent asthma. Clinical significance ≥ 1 unit in TDI scores from BDI (represented by arrow line) $P > 0.05$ not significant by the Kruskal-Wallis test. Values represented as mean and 95% confidence interval (Y error bars), FP: Fluticasone propionate, BDP: Beclomethasone dipropionate, BUD: Bbudesonide

there was no chance of contamination from previous use of ICS. Although LABA is not recommended according to the present GINA guidelines for patients in grade-II severity, it was used to maintain treatment uniformity among study population. Post study power calculations revealed a power of 96% at = 0.05. In the preliminary results of this study published earlier[16] comparing fluticasone and beclomethasone/BUD in 96 subjects followed up for 3 months demonstrated an early response in QoL scores in favor of fluticasone as compared to beclomethasone/BUD in subjects with moderate to severe asthma. In this communication, we present a larger group of subjects with adequate sample size in each group, a longer follow-up (6 months), and with additional data on dyspnea indices.

Spirometry

Two long-term studies[17] (> 6 months) comparing effect of different ICS on FEV_1 are cited in the Cochrane review. The duration of 15 other studies[16] identified ranged from 4 to 12 weeks. The absolute FEV_1 and the change in FEV_1 did not show any significant difference ($P > 0.05$) in patients with varying severity of asthma between three ICS except in the Ige-2002 study,[18] which favored BDP.

Six other studies[19] assessed absolute FVC and change in FVC from baseline, varying from 4 to 12 weeks, in patients with mild, moderate, and severe persistent asthma. Pooled values showed a significant difference ($P < 0.05$) in improvements of absolute FVC values and change in FVC from baseline in favor of fluticasone. We did not observe any significant ($P > 0.05$) difference in absolute FVC and FEV_1 values as well as a change in FVC and FEV_1 values from baseline between the three ICS over 6-month follow-up period.

Health-Related Quality of Life Improvement

Baseline SGRQ scores in our study population was higher compared to baseline scores of other asthma studies where the SGRQ was the QoL instrument[1,3] possibly due to our subjects being treatment naïve. After treatment with ICS, there was a significant decrease ($P < 0.05$) in SGRQ scores reflecting improved QoL in all three-treatment groups. Two of the earlier studies using AQLQ[20] and ACQ[21] have shown an improvement in QoL scores in favor of fluticasone. These studies included moderate to severe persistent asthmatics, whereas our study included patients with mild, moderate, and severe persistent asthma. The significant improvement noted with FP compared to BUD and BDP in HRQoL was due to its effect on moderate and severe persistent asthma. In mild persistent asthma, the improvement was comparable between the three ICS.

ICS influence on HRQoL Domains

On analysis of different domains of the SGRQ, a significant difference favoring FP was noted in the activity and impact scores, which deal with patient determinants

when the lungs are stressed, while symptoms score deal with determinants predominantly in the resting state. This observation could be due to higher potency of fluticasone as compared to other ICS[22] which possibly resulted in a rapid clinical response. This highlights the importance of monitoring outcome measures such as QoL, which measures different aspects of disease in the resting state as well as at various levels of exertion, so that subtle, yet clinically important differences between drugs can be recognized. On the other hand, the symptom scores mirrored pattern of change in FEV_1, and were comparable between the three ICS, probably because both parameters are measured at the resting state.

Effect of ICS on Varying Severity of Asthma

Patients with mild persistent asthma, receiving ICS had significant improvements in their QoL compared to baseline by 15th day, which was comparable between the three groups, until 4 months. However, at the end of 6 months, FP showed a significant improvement in impact, activity, and total scores as compared to BUD and BDP. In moderate persistent asthmatics, a significant improvement from baseline in QoL was observed by 15th day that continued till 60th day, and FP was found to be equivalent to BUD and significantly ($P < 0.05$) better than BDP. Subsequently, the three ICS were comparable except at the end of study where FP was found to be better than BDP, but not BUD. In patients with severe persistent asthma, no statistically significant difference could be demonstrated between three groups, throughout the study period, though there was clinically significant improvement in favor of FP in all three domains of the SGRQ, both on day 15 and at the end of study.

BDP-treated patients with mild and moderate persistent asthma, showed an unexpected decline at end of study in overall QoL scores, as observed in activity and impact domains, which may be due to acute exacerbations that were observed in patients receiving BDP just before the last follow-up. Compared to BUD and FP, the BDP-treated group documented 19 acute exacerbations between visit-7 and visit-8 (end). This was reflected in HRQoL scores, but not in lung functions or dyspnea assessments possibly the reason was that the SGRQ assessed HRQoL in the previous month, while lung functions were currently measured during visits.

Dyspnea Impairment

As a standard measure for dyspnea, BDI-TDI is capable of evaluating dyspnea caused by the magnitude of exertion that evokes dyspnea.[23] The time taken to reach a change of 1 unit in TDI is an important outcome measure in asthma. Fluticasone showed an early response (≥1 unit from BDI) in dyspnea reduction in asthma patients within 15–30 days of treatment. This response of FP was statistically significant ($P < 0.05$) at 15th day compared to BDP but not to BUD ($P > 0.05$). Patients of BUD and BDP groups showed a clinically significant (≥1 unit from BDI) dyspnea reduction only after 45 days of treatment. This might have reflected in the early response in QoL scores noted for fluticasone.

CONCLUSION

Our study demonstrated that SGRQ and BDI-TDI are useful outcome measures in asthma studies and are able to measure dimensions not measured by pulmonary function tests that help to identify subtle differences between drugs. All the three ICS showed improvement in lung functions and QoL scores. The early response in quality of life improvement with fluticasone was observed in patients with moderate and severe persistent asthma. More studies comparing different disease-specific instruments such as AQLQ and SGRQ are necessary to identify the ideal HRQoL measure in asthma.

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