Pharmaceutical Care Services for Asthma Patients: A Controlled Intervention Study

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As asthma is associated with an enormous social, psychological, and economic burden, various patient education programs have been developed to improve outcomes, including quality of life. The authors evaluated the effectiveness of community pharmacy-based interventions on lung function, health-related quality of life, and self-management in asthma patients in a 12-month controlled intervention study in 26 intervention and 22 control pharmacies. Pharmacies opted whether to take part as intervention or control pharmacies. According to this, patients (ages 18-65) with mild to severe asthma attending the pharmacies were allocated to the intervention (n = 161) or control group (n = 81), respectively. Intervention patients were educated on their disease, pharmacotherapy, and self-management; inhalation technique was assessed and, if necessary, corrected. Pharmaceutical care led to significantly improved inhalation technique. Asthma-specific quality of life and the mental health summary score of the SF-36 improved significantly in the intervention group. At 12 months, the intervention group showed significant improvements with regard to evening peak flow, self-efficacy, and knowledge.

Journal of Clinical Pharmacology, 2001;41:668-676

Asthma is one of the major health problems in industrialized countries.[1,2] As asthma is associated with an enormous social, psychological, and economic burden, various patient education programs have been developed to improve outcomes, including quality of life. Although new pharmacological agents and therapeutic guidelines have been developed over the past years, no major improvements in terms of morbidity and mortality could be established.[3]

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Patient education programs are frequently conducted by physicians or nurses and usually take place in clinical settings.[4] However, there are few data about long-term effectiveness. To achieve permanent improvements, it is necessary to provide patient education on a regular ongoing basis. Pharmacists have become more and more active in patient care over the past years and can demonstrate a positive impact on the outcomes of drug therapy in asthma patients.[5,6] Pharmaceutical care is a concept to optimize drug therapy, minimize drug-related problems, and improve self-management and quality of life of patients. The pharmacist is part of the health care team, and extensive communication between pharmacist, physician, and patient is necessary to achieve defined health outcomes.[7,8] Johnson and Bootman[9] referred to the costs resulting from drug-related problems as a "multibillion dollar problem." They estimated the net benefit for the American health care system due to the implementation of pharmaceutical care to be approximately $40 billion. The present study is the first controlled trial to investigate the impact of pharmaceutical care for asthma patients in Germany.

METHODS

Setting

All of the 465 community pharmacies in the city of Hamburg (population 1.7 million) were asked to enter the study either as an intervention or control pharmacy; 26 and 22 pharmacies, respectively, agreed to participate. Intervention pharmacies were asked to deliver pharmaceutical care in one-to-one meetings in counseling rooms.

Participants

At the beginning of the study, the intervention pharmacies were trained to provide pharmaceutical care and were introduced to the study protocol. Training of the intervention pharmacist comprised medical, pharmaceutical, and pharmacological knowledge (5 hours), communication skills (6 hours), and the use of the study protocol and documentation forms (2 hours). In contrast to other patient education programs in primary care, pharmaceutical care is an individual approach. Pharmacists did not follow a predefined educational program but aimed to detect and solve individual drug- and health-related problems. The control pharmacies received an introduction to the study protocol only.

Sample Size

Minimum sample sizes for different potential analyses were calculated using the methods described by Cohen[10] with a predetermined alpha level of $\alpha = 0.05$, a power $1 - \beta = 0.8$, and an effect power ranging from $d = 0.3$ to $d = 0.6$. According to these calculations, the smallest sample size can be estimated at 121 cases for a Pearson's χ^2 test ($df = 3$) and at about 23 cases for a two-way analysis of variance with repeated measurements for two groups (intervention and control).

Patients' Assessment

The intervention and control pharmacies recruited 161 and 81 patients, respectively. Asthma patients were identified by means of their medication or by patients' self-reports. Patients gave written informed consent, which was developed in cooperation with the data protection agency in Hamburg. Afterward, patients and pharmacists asked the physicians in attendance ($n = 120$, general practitioners, internal medicine and pulmonary specialists) for their willingness to cooperate. The diagnosis was confirmed by the physician by means of spirometry results. The Medical Research Council Dyspnea Scale (Medical Research Center—MRC of Great Britain, 1960) was used to assess dyspnea severity (none to severe: 0-4), and asthma severity (mild to severe: 1-3) was classified according to German Asthma Guidelines.[11] In addition, patients rated their self-perceived asthma severity and dyspnea at 6 and 12 months in accordance with the same criteria. Lung function data were reviewed independently by two experienced chest physicians. In case of insufficient or apparently incorrect data, physicians were asked to provide flow volume curves. These patients' data were reassessed by the chest physicians. Data that still could not be interpreted have been excluded. In addition, the chest physicians checked the lung function data and asthma severity for consistency. After 6 and 12 months, this procedure was repeated.

Data Collection and Interventions

Meetings between pharmacists and patients in the intervention group were scheduled at 6-week intervals (overall, 9 meetings within 12 months). During these meetings, the pharmacists assessed and, if necessary, corrected patients' inhalation techniques. In addition, pharmacists detected and solved drug- or health-related problems in cooperation with the patient and the physician (Table I).

To improve self-management, study patients were instructed to use a peak flow meter provided for the study and an asthma diary on a regular basis. The control group received traditional care. At baseline and after 6 and 12 months, quality-of-life questionnaires, a self-efficacy questionnaire, and an asthma knowledge questionnaire were administered to all patients.

Outcome Measures

To demonstrate the impact of pharmaceutical care, the following outcome measures were chosen. To monitor lung function, forced expiratory volume in 1 second (FEV_1) and peak expiratory flow rates were measured. The percentage change in FEV_1 from baseline was used as a clinical outcome.[3] Peak expiratory flow rates were measured by patients at home and on consulting dates in the pharmacy as a means of self-monitoring. The peak flow measures under pharmacists' supervision were recorded in the monitoring plan. In addition, study patients' diaries (peak flow measurements twice a day) were analyzed. For statistical analysis, the mean of 5 consecutive morning and evening values at baseline and at 6 and 12 months, respectively, was taken. A

Table I Drug-Related Problems and Solutions (case reports from intervention pharmacies)

Problem	Example	Solution
Need for additional drug therapy	Patients without inhaled corticosteroid but needing one	Referral to physician
Inappropriate dosage form	Patients unable to use a metered dose inhaler	Use of dry-powder inhaler or breath-activated device
Dosage too low	Patients using the inhaled corticosteroid every other day	Information on the proper and regular use
Dosage too high	Patients with excessive use of short-acting beta2 agonists	Information on the use of controller and reliever medication
Adverse drug reaction	Patients with sore throats or thrush caused by the use of inhaled corticosteroid	Use of spacer and mouth rinsing
Interactions	Self-medication with NSAIDs	Switch to paracetamol if possible
Compliance	Patients refusing the use of inhaled corticosteroids due to the fear of systemic side effects	Patients were informed on the differences between inhaled and oral corticosteroids

7-point checklist was used to score the inhalation technique. For each correct step, 1 point was assigned, and the sum score of the inhalation technique was documented. The SF-36 and the German version of the Living with Asthma Questionnaire[12,13] were applied to measure generic and asthma-specific quality of life, respectively. A constructed self-efficacy scale based on parts of a standardized generic self-efficacy questionnaire[14] and some disease-specific items was employed to investigate any changes of patients' perceptions in their self-management skills and ability to deal with the disease.

The asthma knowledge questionnaire, which focuses on basic information about the disease and drug therapy, was developed in cooperation of chest physicians, clinical psychologists, and clinical pharmacists involved in this study.

Statistical Analysis

Statistical computations were performed on 164 patients using statistical analysis systems (SAS® version 6.12, SPSS® version 8.0, STATISTICA® version 5.1H; all for Windows NT).

To examine various hypotheses concerning the effect of pharmaceutical care, it was necessary to take different statistical techniques into consideration. A variety of tests were considered according to the assumptions used in the tests (e.g., uni- and multivariate distribution, covariance/variance). The ones chosen were those with the most power for each type of hypothesis.

The comparability of uniquely measured demographic data (e.g., gender, age, age of onset, allergic status, etc.) between the intervention and control group was investigated by Pearson's χ^2, Student's independent *t*-test, Mann-Whitney's U-test, or Wald-Wolfowitz's runs test, while the repeatedly measured outcome parameters (e.g., spirometric data, physiological and psychological scales) were analyzed by single comparisons within the general mixed models (SAS® 1990; proc-mixed) or Cochran-Mantel-Haenszel's χ^2-test, respectively, which were used to evaluate the effectiveness of intervention.

All scales and subscales derived from the repeatedly administered questionnaires (quality of life, self-efficacy, knowledge) were linearly transformed to a percentage scale ranging from 0 to 100. Low values are associated with a low characteristic of the measured construct and vice versa.

For all statistical analysis, the two-tailed alpha level was predetermined on $\alpha = 0.05$. The hypotheses on parameters concerning the trend of the intervention and the control group over time (e.g., lung function, quality of life, self-efficacy, knowledge, and inhalation technique) were investigated using general mixed models (SAS® 1990; proc-mixed) or the nonparametric Cochran-Mantel-Haenszel's χ^2 test if any assumption of the mixed models was violated.

RESULTS

At the beginning of the study, the intervention pharmacies recruited 161 patients, and the control pharmacies

Table II Baseline Characteristics of Intervention and Control Group

Variable	Intervention Group (n = 101)		Control Group (n = 63)		p-Value
Mean (*SD*) of age (years)[a]	46.3	(11.4)	45.9	(12.5)	0.976
Sex (%)[b]					0.394
Female	66	(65.4)	37	(58.7)	
Male	35	(34.6)	26	(41.3)	
Employment status (%)[b]					0.508
Employed	61	(62.9)	31	(57.4)	
Unemployed	36	(37.1)	23	(42.6)	
Smoking status (%)[b]					0.156
Current smoker	28	(28.9)	10	(18.2)	
Ex-smoker	31	(32.0)	15	(27.3)	
Nonsmoker	38	(39.1)	30	(54.5)	
Asthma severity (%)[b]					0.814
1—mild	47	(50.0)	30	(49.2)	
2—moderate	35	(37.2)	25	(41.0)	
3—severe	12	(12.7)	6	(9.8)	
Mean (*SD*) of asthma severity	1.63	(0.7)	1.61	(0.7)	
Type of asthma (%)[b]					0.009
Allergic	28	(31.1)	6	(10.0)	
Nonallergic	21	(23.3)	16	(26.7)	
Mixed type	41	(45.6)	38	(63.3)	
Physician in attendance (%)[b]					0.01
General practitioner	50	(49.5)	16	(25.8)	
Specialist in internal medicine	22	(21.8)	18	(29.0)	
Chest physician	29	(28.7)	28	(45.2)	
Mean (*SD*) of age when asthma was diagnosed (years)[a]	32.1	(15.1)	32.2	(16.2)	0.838
Mean (*SD*) of duration of asthma since onset (years)[a]	13.7	(11.4)	13.7	(11.2)	0.884
Mean (*SD*) of FEV_1 %VC[c]	67.6	(15.7)	70.5	(14.7)	0.266

FEV_1 %VC, percentage forced expiratory volume in 1 second of vital capacity (Tiffeneau index). Numbers do not always add up to total because of missing data.
a. Mann-Whitney U-test.
b. Pearson's χ^2 test.
c. Student's *t*-test.

recruited 81 patients. After the application of the study criteria (intervention and control group: patient-pharmacist meeting at baseline and meetings after 6 and 12 months were mandatory; intervention group only: no more than two missed meetings in a row and no more than three meetings missed within 12 months), 101 patients remained in the intervention group and 63 patients served as controls. To control for confounders and biases, a wide range of baseline characteristics and outcome measures were recorded and tested for group differences. The only significant differences at baseline were physicians in attendance and type of asthma (Table II). Significantly more patients (n = 28, 45.2%) in the control group were treated by a chest physician than in the intervention group (n = 29, 28.7%). In only 6 (10%) patients in the control group was allergic asthma diagnosed against 28 (31.1%) in the intervention group (p = 0.009). At entry, there were no significant differences regarding the outcome measures. Hence, it seems justified to deduce that the observed significant changes in the outcome measures were due to the intervention. Patients mentioned mainly the lack of interest (29.5%, n = 23) or the lack of time (22%, n = 17) as reasons to discontinue.

Lung Function, Dyspnea, and Asthma Severity

Although the FEV_1 was clearly increased in the intervention group at 6 months (+11.4% vs. +4.5% change

from baseline in the control group), no significant difference in comparison to the control group could be established at 12 months.

Peak expiratory flow rates measured in the pharmacy remained unchanged. In the intervention group, the morning values recorded in patients' diaries remained unchanged, but the evening values increased significantly. The changes in dyspnea and asthma severity rated by physicians were not significant. In contrast, the patients in the intervention group perceived a significant within-group improvement of asthma severity from 6 to 12 months. These improvements differed significantly from the control group at 12 months (Table III).

Inhalation Technique, Knowledge, and Self-Efficacy

Inhalation technique improved significantly in the intervention group. Though no significant change with regard to knowledge of asthma and drug therapy could be determined at 6 months, at 12 months, the knowledge in the intervention group was significantly improved. Self-efficacy was improved in the intervention group at 6 ($p = 0.019$) and 12 months ($p = 0.001$) (Table IV).

Quality of Life

In the intervention group, the mental summary scale of the SF-36 improved significantly while the physical summary scale indicated no change. Significant improvements could be established for the intervention group in the summary score and all subscales of the Living with Asthma Questionnaire: physical symptoms, psychological distress, and functional status (Table V).

Limitations of the Study

The tendencies for improvements in the control group (Tables III-V) with regard to some outcomes measured at 6 months might indicate that even the control pharmacists engaged in counseling activities. Due to ethical considerations, it did not seem appropriate to stop control pharmacists from intervening if a drug-related or health-related problem became evident.

DISCUSSION

The findings show that pharmaceutical care performed in community pharmacies has a clear, positive impact on the patients' asthma management and quality of life. Moreover, it could be demonstrated that pharmaceutical care is feasible and highly accepted by the patients as a long-term service in primary care.

The small changes in lung function are consistent with the results found in other studies.[15] Although FEV_1 in the intervention group was clearly but not statistically significantly increased at 6 months by 11.4%, a decrease to the control level at 12 months could be observed. Reasons for this remain unclear. A 12% increase in FEV_1 indicates a significant improvement regarding airflow obstruction.[3] So, we regard the 11.4% improvement in FEV_1 during the first 6 months as clinically significant. Though the lung function data indicate no changes at 12 months, one cannot conclude that patient education programs are not effective as morbidity comprises additional parameters (e.g., hospitalizations). Therefore, it is questionable whether measuring FEV_1 only three times during a period of 1 year accurately reflects morbidity.

As in previous studies, it could be demonstrated that pharmacists may improve patients' inhalation techniques.[16] Although this is just a technical aspect of patient education, it is one of the prerequisites for achieving positive outcomes of drug therapy as up to 60% of the patients do not use their inhalers correctly.[17]

Beyond this, the pharmacists' interventions aimed to provide patients with deeper insights into their disease and drug therapy. Therefore, the disease- and health-related problems were discussed in individual counseling sessions. It is arguable whether improved knowledge will lead directly to increased self-management in asthma patients,[18] but it is definitely a good basis for safe and rational drug use.

One of the most important conditions for the patient's ability to cope with asthma is his or her self-confidence with respect to his or her own capabilities to effectively alter the disease process. Therefore, the detected improvement in self-efficacy is a predictor of long-term patient compliance. This might be important in practice, particularly when patients are confronted with a deterioration of their asthma.[19,20]

The increased knowledge and self-efficacy might have led to the positive impact on quality of life. Patients who know more about the disease and drug therapy and perceive more control of their asthma are better prepared to cope with the burden of asthma.[21,22] Probably, these changes in disease perception and attitudes are reflected by the substantially enhanced quality of life.

(text continues on p. 676)

Table III Changes in Forced Expiratory Volume in 1 Second from Baseline, Peak Expiratory Flow Rate, Asthma Severity, and Dyspnea Score in Intervention and Control Groups

	Intervention Group			Control Group			
Variable	**Baseline**	**At 6 Months**	**At 12 Months**	**Baseline**	**At 6 Months**	**At 12 Months**	***p*-Value**
% change FEV_1 from baseline	NA	11.4 (1.5 to 21.4)	6.4 (–2.0 to 14.9)	NA	4.5 (–5.1 to 14.2)	6.7 (–2.6 to 15.9)	Group = 0.475[a] t_0 = 100%[a] t_1 = 0.608[a] t_2 = 0.565[a]
Dyspnea MRCDS 0-4 (rated by physician)	1.25 (1.05 to 1.45)	1.14 (0.93 to 1.35)	1.04 (0.83 to 1.3)	1.21 (0.96 to 1.45)	1.13 (0.86 to 1.41)	1.35 (1.1 to 1.6)	Group = 0.397[a] t_0 = 0.989[a] t_1 = 0.992[a] t_2 = 0.056[a]
Dyspnea MRCDS 0-4 (rated by patient)	Not administered	0.78 (0.61 to 0.95)	0.77 (0.56 to 0.97)	Not administered	0.88 (0.60 to 1.17)	0.96 (0.69 to 1.23)	Intervention group t_1-t_2 = 0.817[b] Control group t_1-t_2 = 0.368[b] t_1 = 0.227[c] t_2 = 0.655[c]
Asthma severity 1-3 (rated by physician)	1.63 (1.48 to 1.77)	1.50 (1.36 to 1.64)	1.48 (1.34 to 1.62)	1.61 (1.44 to 1.78)	1.66 (1.48 to 1.84)	1.66 (1.46 to 1.86)	Group = 0.219[a] t_0 = 0.813[c] t_1 = 0.168[a] t_2 = 0.129[a]
Asthma severity 1-3 (rated by patient)	Not administered	1.51 (1.35 to 1.67)	1.26 (1.12 to 1.40)	Not administered	1.59 (1.37 to 1.81)	1.62 (1.39 to 1.85)	Intervention group t_1-t_2 = 0.008[b] Control group t_1-t_2 = 0.627[b] t_1 = 0.845[c] t_2 = 0.003[c]
PEFR (L/min) (measured in pharmacy)	376 (353 to 398)	379 (357 to 402)	377 (353 to 401)	392 (362 to 422)	392 (356 to 427)	388 (351 to 425)	Group = 0.515[a] t_0 = 0.363[a] t_1 = 0.715[a] t_2 = 0.536[a]
PEFR morning values (L/min) (recorded in asthma diary)	338 (315 to 360)	343 (320 to 366)	345 (321 to 369)	Not administered	Not administered	Not administered	0.382[d]
PEFR evening values (L/min) (recorded in asthma diary)	350 (327 to 373)	361 (338 to 384)	364 (340 to 387)	Not administered	Not administered	Not administered	0.029[d] t_0-t_1 = 0.096[e] t_1-t_2 = 0.890[e] t_0-t_2 = 0.096[e]

Values are means (95% confidence interval). Group = intervention versus control; t_0, t_1, t_2 = intervention versus control at baseline and at 6 and 12 months, respectively. FEV_1 = forced expiratory volume in 1 second; PEFR = peak expiratory flow rate. NA = not applicable.

a. Cochran-Mantel-Haenszel χ^2 test.

b. Wilcoxon test.

c. Pearson's χ^2 test.

d. ANOVA with repeated measurements.

e. Honestly significant differences (HSD) for unequal sample sizes.

Table IV Inhalation Technique, Knowledge, and Self-Efficacy Scores in Intervention and Control Groups

	Intervention Group			Control Group			
Variable	**Baseline**	**At 6 Months**	**At 12 Months**	**Baseline**	**At 6 Months**	**At 12 Months**	***p*-Value**
Inhalation technique (range 1-7)[a]	5.4 (5.2 to 5.7)	6.6 (6.4 to 6.7)	6.7 (6.6 to 6.8)	5.3 (5.0 to 5.6)	5.6 (5.2 to 5.9)	5.8 (5.5 to 6.1)	Group = 0.001 t_0 = 0.325 t_1 = 0.001 t_2 = 0.001
Knowledge[b]	74.4 (72.8 to 76.1)	80.4 (78.7 to 82.0)	83.4 (81.7 to 85.1)	75.7 (73.4 to 77.9)	77.7 (75.0 to 80.5)	77.0 (74.4 to 79.7)	Group = 0.052 Interaction = 0.001 t_0 = 0.263 t_1 = 0.084 t_2 = 0.001
Self-efficacy[b]	56.4 (53.0 to 59.7)	65.1 (62.3 to 67.9)	66.7 (64.0 to 69.5)	56.3 (51.9 to 60.8)	59.7 (55.5 to 63.8)	59.4 (55.8 to 63.1)	Group = 0.05 Interaction = 0.001 t_0 = 0.985 t_1 = 0.019 t_2 = 0.001

Values are means (95% confidence interval). Group = intervention versus control; interaction = Group × Time; t_0, t_1, t_2 = intervention versus control at baseline and at 6 and 12 months, respectively.

a. Cochran-Mantel-Haenszel χ^2 test.

b. SAS® proc-mixed.

Table V Quality-of-Life Scores in Intervention and Control Groups

	Intervention Group			Control Group			
Quality-of-Life Variable	**Baseline**	**At 6 Months**	**At 12 Months**	**Baseline**	**At 6 Months**	**At 12 Months**	***p*-Value**
Generic (SF-36)							
Physical summary scale[a]	37.7 (36.4 to 39.0)	39.0 (37.5 to 40.5)	38.9 (37.6 to 40.3)	37.8 (36.1 to 39.5)	38.5 (36.7 to 40.3)	37.6 (35.8 to 39.4)	Group = 0.490 Interaction = 0.658 t_0 = 0.959 t_1 = 0.461 t_2 = 0.353
Mental health summary scale[b]	43.1 (40.9 to 45.2)	45.3 (43.4 to 47.3)	45.6 (43.6 to 47.6)	41.9 (39.6 to 44.1)	42.0 (39.2 to 44.8)	42.8 (40.1 to 45.5)	Group = 0.003 t_0 = 0.224 t_1 = 0.028 t_2 = 0.044
Living with Asthma Questionnaire							
Physical symptoms[b]	53.5 (48.4 to 58.6)	62.3 (57.4 to 67.3)	64.9 (59.9 to 69.9)	50.5 (43.8 to 57.1)	54.0 (47.5 to 60.4)	54.7 (48.1 to 61.3)	Group = 0.04 t_0 = 0.808 t_1 = 0.009 t_2 = 0.109
Psychological distress[b]	63.3 (59.1 to 67.5)	70.1 (66.4 to 73.9)	72.1 (68.1 to 76.1)	58.9 (53.3 to 64.4)	61.7 (55.8 to 67.7)	59.5 (53.5 to 65.5)	Group = 0.001 t_0 = 0.548 t_1 = 0.006 t_2 = 0.004
Functional status[b]	54.5 (49.3 to 59.7)	61.0 (55.8 to 66.1)	60.8 (55.4 to 66.1)	50.2 (43.8 to 56.5)	53.6 (46.9 to 60.4)	52.9 (45.5 to 60.3)	Group = 0.011 t_0 = 0.416 t_1 = 0.019 t_2 = 0.095
Sum score[a]	58.1 (53.6 to 62.5)	65.5 (61.2 to 69.8)	66.6 (62.2 to 70.9)	53.7 (48.1 to 59.3)	56.8 (50.9 to 62.6)	55.8 (49.6 to 62.0)	Group = 0.018 Interaction = 0.003 t_0 = 0.280 t_1 = 0.009 t_2 = 0.002

Values are means (95% confidence interval). Group = intervention versus control; interaction = Group × Time; t_0, t_1, t_2 = intervention versus control at baseline and at 6 and 12 months, respectively.
a. SAS® proc-mixed.
b. Cochran-Mantel-Haenszel χ^2 test.

There is only a low correlation between increases in quality of life and lung function in patients with asthma and chronic obstructive pulmonary disease.[23,24] On the other hand, the subscales of the Living with Asthma Questionnaire show a clear relationship to asthma severity.[25] It is possible that the increases in quality of life might indicate a reduction in asthma symptoms.

We conclude that the interventions have laid a basis for appropriate drug use, health attitudes, and health behavior that improves the self-management abilities and quality of life in asthma patients. Based on these results, it deems promising to conduct further research into long-term outcomes and the pharmacoeconomical impact of pharmaceutical care programs.

We would like to thank the participating patients, community pharmacists, and physicians who made this research possible. The whole project was funded by the 34-member organizations of ABDA (i.e., 17 state chambers and 17 associations of pharmacists in Germany).

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