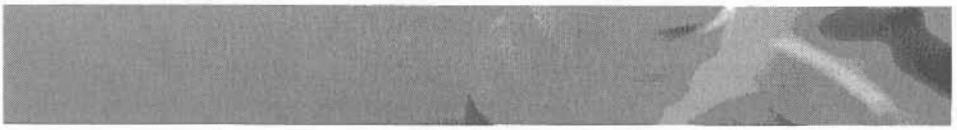

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Research

Randomised controlled trial of general practice based asthma clinics

Adrian R Heard, Ian J Richards, John H Alpers, Louis S Pilotto, Brian J Smith and Julie A Black

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Abstract

Objective: To compare the effects on asthma morbidity of asthma clinics based in general practice with standard general practice care.

Design and setting: A randomised controlled trial in eight general practices. Patients, general practitioners and outcomes assessors were not blinded to treatment allocation.

Participants: 195 patients with asthma aged 5-64 years; 191 completed the trial.

Intervention: Three asthma clinic sessions over six months involving nurse counselling, education about asthma management, spirometry and consultation with the general practitioner.

Main outcome measures: Patients reporting days lost from work or school, number of days lost, the presence of morning or nocturnal asthma symptoms, use of an action plan, medication use, current smoking, hospitalisation, and emergency visits.

Results: Asthma clinics were associated with a greater reduction in nocturnal symptoms, an increase in the ownership of peak flow meters and an increase in the number of patients commencing or resuming smoking. Both control and intervention groups showed similar improvement in days lost from work or school, the presence of symptoms, use of an action plan and taking reliever medication.

Conclusion: Our study does not show that asthma clinics are more effective than standard general practice care in reducing asthma morbidity. It is uncertain how much of the improvement in outcomes was due to the asthma clinic, the influence of the study itself upon patients and practitioners, or other factors, such as the tendency for a patient's asthma management to improve over time.

Introduction

Asthma is the most common chronic disease in children and a leading cause of morbidity in adults in Australia.[1,2] Asthma clinics may be a way of improving comanagement practices between health professionals and people with asthma. They involve trained nurses conducting asthma education, peak flow readings and spirometry with asthma patients, combined with a brief general practitioner

review.

Asthma clinics are an integral part of general practice in the United Kingdom, but have yet to gain acceptance in Australia.[3] One reason for this might be that studies have not provided conclusive evidence that these clinics reduce morbidity.[4-9] This may be because regular general practitioner review[10] and/or asthma education[11] is the key element in reducing asthma morbidity, and therefore only studies comparing asthma clinics with patients receiving irregular reviews are likely to show significant differences in outcomes.

In this study, we used a randomised controlled trial design to test whether asthma clinics (intervention) were more effective in reducing morbidity from asthma than standard medical treatment (control). The clinics used the Patient Management System, a recognised model for operating asthma clinics.[12]

Methods

Ethical approval

Ethics approval for the study was obtained through the Royal Australian College of General Practitioners' ethics committee at the RACGP national office.

Recruitment

A previous major study of asthma self-management found a 50% reduction in the number of people reporting at least one day lost from work.[6] We calculated that to detect a similar reduction in a study with 80% power and a 95% confidence interval a sample size of 170 was required.

Patients were recruited from eight general practices staffed by 42 general practitioners. Consent was sought from all people with asthma aged 5-64 years attending these practices during three months of 1997.

Subjects were individually randomised within practices into intervention and control groups. This meant that each participating general practitioner potentially saw both intervention and control patients. A randomisation chart was set up for each participating practice at Asthma South Australia, and general practitioners and the asthma educators were informed of a subject's treatment allocation before the baseline interview. Thus, patients, doctors and outcome assessors were not blinded as to who had received the intervention and who were controls.

Intervention

Each general practice operated one three-hour asthma clinic session per week. The asthma educators in the trial were practising registered nurses with extensive experience in respiratory care. Their component of the clinic session involved education in asthma management strategies, including a written asthma management plan, spirometry and instruction on using peak flow meters, inhalers and an asthma diary card. The session ended with a consultation by the general practitioner. Each asthma clinic patient was asked to attend three asthma clinic sessions within the six months of the study.

Gathering outcomes data

We conducted a telephone interview using adapted questions from the Southampton Morbidity Index[13] and questions relating to clinical practice[14] at the beginning and end of the study. Our outcome measures included number of patients reporting days lost from work or school, number of days lost, use of an action plan, medication use, current smoking, the level of morning or nocturnal asthma symptoms, hospitalisation, emergency visits, and number of home visits by the general practitioner.

Data analysis

All data were analysed on an intention-to-treat basis.

For analysis, we categorised morning and nocturnal symptoms as "at least weekly" or "less frequently/never" to distinguish regular from irregular symptoms and to maintain adequate numbers of participants in each of the two categories. We analysed the number of days lost from work with both linear and logistic regression. Linear regression was conducted on the difference in the number of days lost from work between baseline and six months, and was adjusted for clustering by doctor. For logistic regression, also adjusted for clustering by doctor, the variable was divided into two categories (two or fewer days lost and three or more days lost), representing better-controlled and less well controlled asthma, respectively.

The statistical analyses for all other study factors used logistic regression, adjusted for baseline measurements and clustering by treating doctor. We also conducted a longitudinal analysis using χ^2 tests to examine changes in the intervention and control groups over the six months of the trial.

Odds ratios and 95% confidence intervals (95% CIs) were calculated for all outcome measures. All tests were conducted using the Stata statistical software package.[15]

Results

Patients

Over the three-month recruitment period, 195 people entered the study, and 191 (97 in the clinic group and 94 controls) completed both interviews (Box 1). The demographic profile of the control group (mean age, 26.3 years, 95% CI, 22.3-30.2; proportion of males, 45%, 95% CI, 34%-55%) was similar to the intervention group (mean age, 27.5 years, 95% CI, 23.6-31.4; proportion of males, 42%, 95% CI 32%-52%). Although there were no records of the number of eligible subjects across all participating practices, an audit of all patients seeing general practitioners at two of the eight practices showed a participation rate of 45.1% of all asthmatics. The main reasons for non-participation were either the general practitioner's failing to ask the patient for consent or the patient's refusing consent. The average age of non-participants (mean age, 20.8 years, 95% CI 17.1-24.5) was not significantly different from that of participants (mean age, 21.4 years, 95% CI 17.1-25.7) in the two audited practices. Of the 97 people in the clinic group, 67 completed the three planned clinic sessions, 17 attended only one or two sessions, and 13 failed to attend any sessions.

Outcomes

There was no difference between the clinic and control groups at baseline for dichotomous study variables (Box 2), which provided evidence for effective randomisation. There was a low incidence of hospitalisation and emergency department attendance in both groups. At six months, however, waking at night at least weekly due to asthma and current smoking were significantly different between the two groups, as was ownership of a peak flow meter (Box 3). There were no differences reported at six months in patients' having discussed trigger factors with their general practitioner or receiving an action plan from their general practitioner.

Unlike the dichotomous outcome variables, the mean number of days lost from work was significantly different between the treatment groups at baseline, with a high level of variability in the control data (intervention group mean, 2.62, 95% CI 1.84-3.40; control group mean, 5.37; 95% CI 3.46-7.29). There was no

difference in the number of days lost from work at six months in the intervention group compared with the control group (intervention group mean, 2.09, 95% CI 0.91-3.27; control group mean, 2.66; 95% CI 1.66-3.66). Linear regression to compare the number of days lost at six months minus those at baseline between intervention and control participants showed a significant reduction in number of days lost in the control group compared with the intervention group ($P = 0.04$). Logistic regression comparing two or fewer days lost with three or more days lost showed a non-significant trend towards fewer days lost from work at six months in the intervention group (odds ratio, 0.50; 95% CI 0.24-1.03). Longitudinal analyses within the clinic and control groups showed a trend towards decreasing morbidity over the six-month period, with a 13% decrease in the number of people reporting days lost from work, school or usual activities in both groups (intervention group odds ratio, 0.57, 95% CI 0.31-1.06; control group odds ratio, 0.57, 95% CI 0.31-1.06). Longitudinal analyses also showed that the reported issuing of action plans increased significantly in both groups (intervention group odds ratio, 11.25, 95% CI 3.07-41.21; control group odds ratio, 3.94, 95% CI 1.53-10.10). An increase in the discussion of trigger factors was only significant for the control group (intervention group odds ratio, 2.6, 95% CI 0.84-8.02; control group odds ratio, 3.72, 95% CI 1.36-10.21).

Discussion

Our study does not show that asthma clinics are more effective than standard general practice care in reducing asthma morbidity. We observed an improvement in most of the outcome measures in both the intervention and control groups. Outcomes for patients who attended an asthma clinic had few differences from those in the control group.

The intervention group was less likely to be woken "at least weekly" at night due to asthma. This may signal better home management of asthma in the intervention group, an outcome that is anticipated by guidelines[16] but challenged in recent studies.[17] Ownership of peak flow meters increased among the intervention group during the course of the study, probably because the asthma educators promoted the use of peak flow readings for asthma self-management.

More people in the intervention group either adopted or recommenced smoking during the study. Smoking cessation advice was not included as part of the study intervention. In intensive interventions such as asthma clinics, smokers should be identified to ensure that smoking cessation is achieved or maintained if possible.

In this study there were few reports of hospitalisations and emergency department visits at baseline, reflecting our broad inclusion criteria, which did not focus on severe asthmatics. Outcomes which were infrequent in this study may be significant in much larger studies.

In relation to days lost from work or school, the significant difference between the intervention and control groups at baseline, the high variability at baseline in the control group and the different findings between the logistic and linear regressions at six months do not allow an adequate understanding of the effect of the intervention.

The lack of difference between groups in the proportion of participants who had discussed trigger factors with their doctor and who had received an asthma action plan raises one of the possible explanations for the limited differences observed in

this study. Baseline levels of both these clinical practice indicators are usually around 40%-60%,[14] and were within that range at baseline in our study. Yet the frequency of both indicators increased substantially over the six months for both groups, which might suggest that clinical practice for the control subjects was contaminated as a result of general practitioners' seeing both intervention and control subjects.

Other explanations may be:

- The asthma clinic in itself makes no difference to the outcomes being measured, and that a simpler intervention, such as regular general practitioner review, is the critical factor. The results of a review of asthma education support this.[10] Whether the presence of an asthma clinic in a general practice increases the rate of general practitioner review is unknown.

- A possible Hawthorne effect.[18] With general practitioners and patients being unblinded to the study, it is possible that both increased behaviours which led to better asthma self-management outcomes.

- People with asthma tend to show improved outcomes over time. This effect is likely to be enhanced after a visit to a general practitioner where management decisions are made. The data showing that the number of people reporting days lost from work or school decreased in both intervention and control groups support this explanation.

- Baseline data may have been biased because subjects were randomised into treatment groups before the baseline interview, and some subjects may have been aware of their treatment status at the baseline interview.

Whatever reasons led to the apparent improvement in outcomes, a factor that may have contributed to the lack of difference between intervention and control groups may be the poor compliance with the intervention regimen. Nearly one-third of patients from the intervention group did not comply with the required three clinic visits, and 13% did not attend any visits.

The outcome of this study holds some lessons for future randomised controlled trials in general practice. The major limitation of the study was the randomisation by patient rather than practice, which may lead to modification of general practitioner behaviour towards the control group as well as the intervention group, thus increasing the chance of contamination of controls and the Hawthorne effect.

The inability to blind general practitioners and patients to the patient's treatment allocation also limited the study.

The participation rate of less than 50% is lower than the rate considered desirable for randomised controlled trials, but compares favourably with other community-based studies.[6,19]

This study also demonstrates that, in general practice, larger, longer-term or more targeted studies (such as to more severe asthmatics) are required to show differences, especially for variables such as hospitalisation for asthma, which have

a relatively low incidence among most general practice patients. Conducting this study for a longer period would also have allowed it to run over the full range of seasons, which is preferable for studies of seasonal diseases such as asthma.

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Authors' details

SA HealthPlus, Department of Human Services, Adelaide, SA.
Adrian R Heard, BSocAdmin, MPH, Senior Project Officer.

Centre for Health Care Evaluation, Bedford Park, SA.
Ian J Richards, BApplSc, MPH, Project Officer.

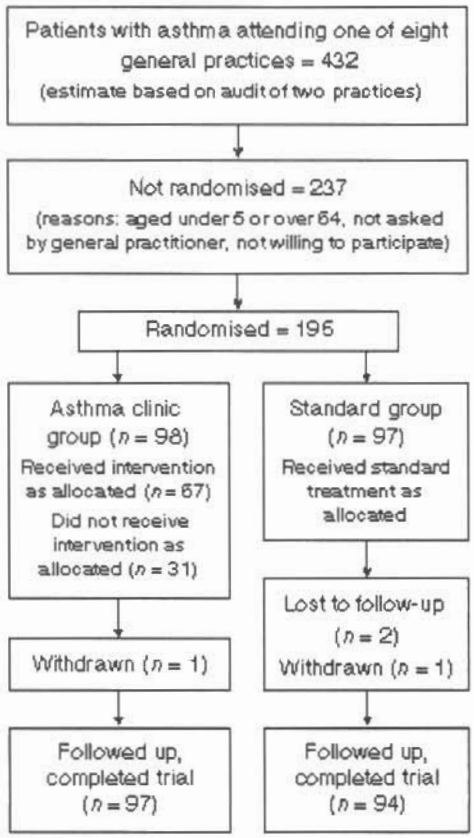
Flinders Medical Centre, Bedford Park, SA.
John H Alpers, MD, FRACP, Director, Respiratory Unit.

North Western Adelaide Health Service, Woodville South, SA.
Louis S Pilotto, FAFPHM, PhD, Senior Consultant.
Brian J Smith, FRACP, PhD, Senior Lecturer, Department of Medicine.

Asthma SA, Royston Park, SA.
Julie A Black, BNG, Chief Executive Officer.

Reprints will not be available from the authors.
Correspondence: Mr A R Heard, SA HealthPlus, PO Box 65, Rundle Mall, SA 5000.
Email: Adrian.HeardaATdhs.sa.gov.au

1: Study flow diagram



Back to text

2: Adjusted* odds ratio and 95% confidence interval for outcome measures between control and asthma clinic patients with asthma at baseline

Outcome measure	Proportion of patients		Odds ratio	95% CI
	Control (*n*=94)	Clinic (*n*=97)		
People reporting any time lost from work or school in the last six months	0.52	0.48	0.86	0.49–1.52
Have discussed trigger factors with doctor	0.54	0.60	1.25	0.75–2.09
Have an action plan provided by doctor	0.45	0.49	1.21	0.79–1.87
Taking reliever medication in the last six months	0.90	0.88	0.75	0.39–1.43
Taking preventer medication in the last six months	0.81	0.78	0.86	0.41–1.78
Have a peak flow meter	0.53	0.46	0.76	0.45–1.28
Currently smoking	0.09	0.12	1.51	0.43–5.39
Waking at least weekly in the morning with asthma, wheeze, or cough	0.39	0.28	0.59	0.34–1.05
Waking at least weekly at night due to asthma	0.32	0.19	0.49	0.23–1.02
Hospital admission in the last six months	0.06	0.08	1.32	0.42–4.12
Emergency department visit in the last six months	0.10	0.10	1.08	0.46–2.54
Doctor visit to home in the last six months	0.02	0	†	†

* Adjusted for clustering by doctor. CI = confidence interval.
† Odds ratio indeterminable due to a zero cell.

Back to text

3: Adjusted* odds ratio and 95% confidence interval for outcome measures between intervention and control patients with asthma at 6-month follow-up

Outcome measure	Proportion of patients: Control (*n*=94)	Clinic (*n*=97)	Odds ratio	95% CI
Persons reporting time lost from work or school in the last six months	0.38	0.35	0.92	0.48–1.76
Have discussed trigger factors with doctor	0.76	0.85	1.71	0.87–3.36
Have an action plan provided by doctor	0.65	0.75	1.62	0.82–3.22
Taking reliever medication in the last six months	0.97	0.95	0.65	0.14–2.97
Taking preventer medication in the last six months	0.84	0.81	0.88	0.37–2.09
Have a peak flow meter	0.56	0.73	8.30	2.96–23.27
Currently smoking	0.07	0.15	3.97	1.11–14.25
Waking at least weekly in the morning with asthma, wheeze, or cough	0.33	0.22	0.65	0.32–1.34
Waking at least weekly at night due to asthma	0.20	0.07	0.38	0.16–0.91
Hospital admission in the last six months	0.05	0.02	0.31	0.05–1.75
Emergency department visit in the last six months	0.01	0.03	2.97†	0.28–32.02
Doctor visit to home in the last six months	0.01	0.01	0.97†	0.06–15.80

* Adjusted for baseline measures and clustering by doctor. CI = confidence interval.
† Not adjusted for baseline measures due to zero cells.

Back to text