Evidence-Based Assessment of Educational Interventions: The Importance of the Control Group

Perneger TV, Sudre P, Muntner P, et al. Effect of patient education on self-management skills and health status in patients with asthma: a randomized trial. Am J Med 2002;113:7–14.

Study Overview

Objective. To determine the effectiveness of an educational intervention for adults with asthma.

Design. Randomized controlled trial with an intention-to-treat analysis.

Setting and participants. The study was held at a single institution in Geneva, Switzerland. Consecutive adult patients who were hospitalized for an asthma exacerbation, received asthma medications during a hospitalization, or were seen in the emergency department with an asthma exacerbation over a 30-month period.

Intervention. The educational intervention comprised of three 75-minute educational group sessions. In the first session, patients learned how to identify and assess asthma symptoms through asthma trigger identification, environmental control, and peak flow meter monitoring. In the second session, patients received information concerning the mechanisms of asthma and the purposes of specific asthma medications. In the third session, participants were instructed in the use of an individualized self-management care plan. This plan detailed specific protocols based on symptoms and peak flow measures.

Main outcome measures. The primary outcome was improvement in health and functional status at 6 months' follow-up measured using the SF-36 health survey and Asthma Quality of Life Questionnaire activity score. Secondary outcomes included number of missed work days due to asthma; physical limitations, problems sleeping, emotional problems, social difficulties, or difficulties with work resulting from asthma; smoking status; perceived threat from asthma; level of confidence in treatment and perceived effectiveness of treatment; number of physician visits, emergency department visits, and hospitalizations; and regular use of steroids and β agonist. Patient proficiency in using a spray inhaler and peak flow monitor also was assessed by a trained reviewer.

Main results. Of 311 potential participants, 253 were eligible. 131 patients agreed to participate and were randomized to immediate education ($n = 66$) or to the control group (6-month waiting list; $n = 65$). Only 33 (50%) completed all 3 sessions and 8 (12%) patients attended no sessions. 8 (12%) patients in the intervention group and 7 (11%) in the control group were lost to follow-up. There were no statistically significant differences between the 2 groups at baseline with regard to reported patient characteristics. 40 different outcome variables were analyzed, and 26 improved significantly in the intervention group and 19 improved significantly in the control group between the baseline and follow-up period. For the primary outcomes, there was less improvement in the activity score for participants in the intervention education group versus the control group (odds ratio [OR], −0.4 [95% confidence interval {CI}, −0.08–0.0]; $P = 0.03$). In the secondary analyses, the intervention group had statistically significant improvement in correct inhalation techniques (OR, 2.4 [95% CI, 1.0–5.7]; $P = 0.048$), knowledge of peak flow reading that required physician notification (OR, 3.1 [95% CI, 1.4–6.7]), and confidence in treatment (OR, 2.9 [95% CI, 1.0–8.1]) when compared with the control group. Use of health services was similar between the 2 groups.

Conclusion. The educational intervention was not effective at improving overall self-management skills and functional status for patients with asthma.

Commentary

Patient self-management programs have been reported to improve anticoagulation control [1], glycemic control in diabetics [2], and the use of health services in asthmatics [3]. Patient education directed at improving self-management has been recommended as an integral component of asthma management [4]. However, educational interventions can vary

from institution to institution and, therefore, the effectiveness of the intervention also might vary. With this randomized control trial, Perneger et al have demonstrated that some educational interventions, when compared with regular care, might not be effective for improving asthma functional status and reducing health services utilization.

The lack of effect could be related to several other methodologic issues and might not necessarily reflect an ineffective intervention. First, the intervention only involved 3 didactic sessions, which might have been too few sessions to result in patient improved knowledge and self-management skills. Second, the compliance with these sessions was poor, and only half of the participants completed all 3 sessions. 12% of intervention patients attended no sessions at all. Third, the follow-up was fair, with 12% of the patients in the intervention arm and 11% in the control arm being lost to follow-up. It is unclear how this bias might have influenced the results. Fourth, as the authors point out, the control group undoubtedly received some type of educational intervention outside of the study intervention. This education was unmeasured and would bias the results to the null.

Although we cannot draw firm conclusions on whether this was a negative trial due to a lack of intervention effectiveness or a study design flaw, we can draw one very important observation from Perneger et al's trial. Improvements from baseline were seen in both the control and the intervention group. Had this project been conducted without a control group, such as in a quality improvement setting, one might have erroneously ascribed an effect to the intervention.

Applications for Clinical Practice

An educational intervention designed to teach patients self-management skills in adults with asthma did not improve patient functional status or health services utilization. Improvements were seen in both the intervention group and the control group, emphasizing the importance of the control group for assessing educational interventions.

–Review by Harvey J. Murff, MD, MPH

References

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