

Economic analysis of two structured treatment and teaching programs on asthma

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The aims of the present study were as follows:

- 1) to evaluate the medical outcomes of two treatment and educational asthma programs
- 2) to determine by cost-analysis both cost and economic outcome of the programs
- 3) to perform a cost-benefit analysis (determining the net cost-benefit) and a cost-effectiveness analysis (determining the cost per unit of effect and the incremental cost-effectiveness ratio) from the perspective of health program policy makers (HPP: indirect costs, i.e., loss of productivity, excluded) and of society as a whole (SaW: all costs included).

Patients were randomly assigned to a complete (CP; $n=32$) or reduced (RP; $n=33$) program: the RP group received a reduced education (self-reading of an educational booklet on asthma), while the CP group attended an "asthma school", consisting of six lessons based on the same booklet and including educational videotapes. Both programs included peak-flow monitoring and treatment according to international guidelines, and follow-up. The outcome variables (asthma attacks, urgent medical examinations, admission days, working days lost) did not differ significantly between CP and RP. Morbidity savings were \$1894.70 (CP) and \$1697.80 (RP) according to SaW, and \$1349.50 and \$1301.80, respectively, according to HPP. The net cost-benefit was \$1181.50 for CP and \$1028.00 for RP, and the cost-benefit ratio per dollar spent was 1:2.6 for CP and 1:2.5 for RP, according to SaW. One day of admission prevented had a cost of \$110.20 (CP) and \$94.10 (RP). CP gave slightly better results and was slightly more cost-effective than RP in improving patients' welfare. It cannot be excluded that the retrospective analysis used to determine baseline costs might have inflated differences for both groups. Sensitivity analysis was slightly in favor of RP when the outcome variables were tested at their upper and lower 95% CI.

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Asthma is a relevant cause of chronic morbidity, and asthma-induced morbidity and mortality are increasing (1, 2). Asthma has a great economic impact because of the burden it places on health resources and the loss of productivity caused by absence from work (2). The competition of health programs for limited economic resources within national health systems has spawned an abundance of studies on economic evaluation in health care (1, 3). Economic evaluation is the comparative analysis of alternative courses of action in terms of costs and consequences, and is most useful when preceded by efficacy and effectiveness evaluation

(3). Various groups have analyzed the outcome of treatment and teaching programs on asthma (4–6), and others have performed economic evaluations (7–10). Deter (7) found that benefits outweighed costs 5:1. Tougaard and Sondergaard (9, 10) showed lower consumption of health resources after education in chronic obstructive pulmonary disease (COPD) and asthma patients; and Trautner et al. (1), in a cost-effectiveness analysis, showed that a teaching program for patients with asthma yielded economic and medical benefits. Despite the difficulty in comparing asthma programs, there is agreement

that a minimum set of variables (number of asthma crises, urgent medical examinations, admission days, and working days lost) can be used to evaluate the outcome of these programs (8).

The aims of the present study were as follows:

- 1) to evaluate the medical outcomes of two treatment and educational programs, with the above variables
- 2) to determine by cost-analysis both cost and economic outcome of the two programs
- 3) to perform a complete economic evaluation by cost-benefit (determining, separately for both programs, the net cost-benefit) and cost-effectiveness analysis (determining the cost per unit of effect on the above-mentioned variables) and the incremental cost-effectiveness ratio.

Cost-benefit and cost-effectiveness were analyzed from the perspective of health program policy makers (indirect costs such as loss of productivity not included) and of society as a whole (the total cost).

Material and methods

Study design

Asthma patients were randomly assigned to one of two treatment and teaching programs: a complete (CP = "asthma school") or reduced program (RP) from October 1993 to June 1994 in the Departments of Pneumology of the Fondazione Salvatore Maugeri, Clinica del Lavoro e della Riabilitazione, Care and Research Institute (Tradate), and Busto Arsizio Hospital (Busto Arsizio), Italy. The diagnosis of asthma was made according to international guidelines (11).

The outcome of both programs was evaluated with the following variables: number of asthma attacks, urgent medical examinations, admission days, working days lost, and cost of drugs used. Medical outcome was evaluated as follows:

- 1) in CP vs RP, during the years before and after enrolment
- 2) separately in CP and RP, during the year before vs that after enrolment.

The outcome parameters of the year before enrolment were acquired by questionnaire and counter-checked by medical records. Hospitalization and sick-leave data were obtained from sickness funds records (1). Only employed patients were included in the analysis of days of absence from work (1).

The postenrolment data were placed in a database for economic analysis. Cost-analysis is a cost description in which two alternative programs are compared, but the costs and consequences of each alternative are not examined simultaneously (3). Cost-benefit analysis provides an estimate of the

value of resources used by each program compared to the value of resources the program might save or create. It measures both the costs and consequences of alternatives in US dollars (\$). The results of this analysis can be expressed either in the form of a ratio of dollar costs to dollar benefits or as a simple sum representing the net benefit of one program over another. We evaluated the following parameters separately for CP and RP:

- 1) total morbidity cost savings = morbidity cost before - morbidity cost after enrolment
- 2) program cost = initial cost + follow-up cost
- 3) cost-benefit = total morbidity cost savings - program cost
- 4) cost-benefit ratio per dollar spent = program cost / program benefit
- 5) morbidity cost before and after enrolment (3).

In cost-effectiveness analysis, costs are related to a single, common effect that may differ in magnitude between alternative programs. The results of these comparisons are usually stated in terms of cost per unit of effect or of effects per unit of cost. We applied the first option to the above-mentioned outcome variables (3).

Sample size

Eighty patients (40 CP and 40 RP) entered the study, according to a statistical method relating the standardized difference, total study size, and power and level of significance for a two-sample comparison of continuous measurement with the same number of subjects in each group (12). The sample size was calculated from the data of an earlier pilot study conducted by our group (20 patients enrolled in a similar program) (13). Two continuous variables were taken into consideration: a biologic parameter (FEV_1 after enrolment = $94.5\% \pm 15.5$ of predicted; standardized difference = 0.65; significant difference = 10%; with significance at 5% and 85%, the size was 80 patients); and an economic parameter (cost of admission after enrolment = $\$95.45 \pm 427.36$; standardized difference = 0.7; significant difference = $\$307.90$; with significance at 5% and 85%, the size was 70 patients).

Intervention

Forty patients affected by mild, moderate, or severe asthma were randomly assigned to CP or RP at both participating centers. A physician was in charge of the study in each center (A. S.; D. B.); a pretest was conducted in the two centers before beginning the study to minimize any differences that might arise in applying the study protocol. The structure and the cost of the two programs are presented in Table 1. All the patients enrolled in

Table 1. Structure of two treatment and teaching programs on asthma (CP = complete program; RP = reduced program), including time consumption (min), personnel involved in activity (CPHY = chest physician; RTEC = respiratory technician; RTHE = respiratory therapist; PSY = psychologist), and cost in dollars per person

Intervention Initial phase	Time Min	Staff	CP	RP	Cost \$
Medical examination	30	CPHY	Yes	Yes	44
Spirometry	15	RTEC	Yes	Yes	39.3
PEF monitoring	30	RTHE	Yes	Yes	77.5*
Lessons 1-4, 6	4 x 5 x 60	CPHY + RTHE	Yes	no	37.1*
Lesson 5	4 x 60	PSY + CPHY	Yes	No	6.3
Booklet			Yes	Yes	9.2
Follow-up phase					
Medical examination	6 x 30	CPHY	Yes	Yes	264
Spirometry	6 x 15	RTEC	Yes	Yes	235.8
Total cost			713.2	669.8	

*Including cost of peak-flow meter and daily diary.

*Including cost of teaching material.

this study were treated according to international guidelines (11).

Like Ringsberg et al.'s "asthma school" (14), the aims of CP were as follows:

- 1) to systematize asthma treatment, i.e., peak-flow monitoring, recording, and interpretation, and to provide details of drug characteristics, as regards both asthma attacks and basic therapy
- 2) to teach the pathogenesis of asthma and avoidance of exposure to asthma triggers.

The course consisted of six lessons of 1 h each (the first five lessons were held twice a week during the first 2½ weeks after enrolment: a reinforcing lesson was given after 3 months) based on the contents of an educational booklet on asthma (15). Patients enrolled in CP were divided into four groups of 10 patients each for the asthma school lessons. A 20-min educational videotape was shown during lessons 2, 3, and 4. The RP was similar except that the educational intervention was limited to peak-flow monitoring and recording, and self-reading of the educational booklet. Both programs were approved by the competent ethics committee.

Data collection

A custom-designed daily diary for 1 year after enrolment was prepared. The following parameters were collected and stored in a database with the Informix SE DBMS software package on a Compaq 486/25 personal computer: demographic data, lists of drugs used (short- and long-acting β_2 -agonists, oral and nebulized steroids, methylxanthines, antihistaminics, cromons, mucolytics, antibiotics, and immunotherapy), spirometry findings (FEV₁ and FVC), and medical history. The outcome variables were recorded daily by the patients.

Costs and benefits

The impact of both health-care costs (direct costs and benefits) and loss of productivity due to absence from work (indirect costs and benefits) were analyzed when the point of view of society as a whole was considered. Indirect costs were not considered when the perspective of health program policy makers was analyzed (1, 3). Benefits were calculated as the difference between different morbidity costs, and expressed as savings.

Cost-benefit analysis

Program and follow-up costs are reported in Table 1. The exchange rate is \$1.00 = ITL 1623.9 (January, 1995). Personnel-related direct costs were calculated by taking into account the relevant gross salaries (1 min of chest physician = \$0.402; psychologist = \$0.304; respiratory therapist = \$0.266; respiratory technician = \$0.195). The cost of videotapes was \$1.90 per patient, and the cost of room and video recorder rental was \$1.00 per patient per lesson. The direct costs of medical examinations and spirometry were those used in the participating centers, taking into account the refund received from the welfare system in 1994. Since hospital admissions of enrolled patients occurred in different hospitals, a "general per diem" cost of an Italian hospital was calculated from national statistics for 1994: this was \$244.50 (16, 17). Additional diagnostic procedures were not included, so as to obtain a conservative estimate of savings.

Drug costs were based on prices approved by the Italian Ministry of Health in 1994. The cost per unit of drug (puff, tablet, etc.) was determined and multiplied by the total number of doses assumed.

Indirect costs (salary per day of work lost = \$75.00) were estimated according to the monthly gross salary indicated in the national statistics (\$1587.20) (16, 17). For simplification of the model, the medical examinations performed by chest specialists and general practitioners were not differentiated in economic terms.

Cost-effectiveness

After detecting the benefits of both programs, the cost per unit of effect was calculated separately for CP and RP for the outcome measures. The end point of the analysis was the incremental cost-effectiveness ratio, which was calculated by dividing the difference in program costs (CP cost - RP cost) by a divisor corresponding to the difference between the two programs in modifying (reducing) the outcome variables.

Statistical analysis

The outcome variables of both programs (if continuous) were evaluated for normality by the Statgraphics Statistical Package, Version 7.0. Distribution was considered normal when the standardized kurtosis ranged between -2 and 2 . This criterion was satisfied for the cost of drugs only. Student's *t*-test for paired data was used to compare the mean values of drug cost in the same subjects (year before vs year after enrolment). When the comparison was between costs generated by different subjects (CP vs RP costs), the *t*-test for unpaired data was applied. Nonparametric tests were used to analyze the outcome variables, namely, the Wilcoxon test when the comparison was between the same subjects (year before vs year after enrolment), and the Mann-Whitney *U* test when the comparison was done between different patients (CP vs RP outcomes). Expected and observed frequencies were compared with the uncorrected chi-square test. A *P* value less than 0.05 was considered statistically significant. Confidence intervals (CI) for proportions were calculated on the economically relevant variables according to the method of Gardner & Altman (18).

Sensitivity analysis

Sensitivity analysis was performed when a result was uncertain, namely, the economically relevant variables in the year after enrolment. Cost-benefit analysis, from the point of view of society as a whole, was repeated, by applying the upper and lower values of the CI of the key variables (3).

Results

There was no difference between CP and RP in the possible confounding variables (see Table 2). The program cost per patient was \$713.20 for CP and \$669.80 for RP (Table 1). The medical outcomes of both programs are summarized in Table 3. The CI of the proportion of patients without the key variables were as follows:

- 1) urgent medical examinations: CP=0.33 (CI 0.10–0.56); RP=0.56 (CI 0.39–0.73)
- 2) admission days: CP=0.06 (CI 0–0.14); RP=0.07 (CI 0–0.16)
- 3) working days lost: CP=0.06 (CI 0–0.14); RP=0.07 (CI 0–0.16).

There was no statistical difference between CP and RP variables in the years before and after enrolment (Table 3), with the exception of the number of urgent medical examinations in the year

Table 2. Comparison between complete and reduced program for possible confounders, expressed as mean $\pm$ standard deviation, at enrolment. FEV₁ is expressed as percentage of predicted

Program	Complete		Reduced		<i>P</i> value
	Mean	SD	Mean	SD	
Patients enrolled	40		40		
Dropouts	7		8		
Age (years)	47.1	13.9	44.3	7.9	>0.05
Male/female	11/21		14/19		>0.05
Smokers	9		11		>0.05
No. of cigarettes/day	13.9	8.2	12.4	7.7	>0.05
Passive smoking	0.4	0.7	0.3	0.5	>0.05
FEV ₁ at enrolment	78.3	15.3	73.4	16.9	>0.05

after ($P=0.025$). When the outcome variables in the year before vs that after enrolment were analyzed separately for CP and RP, there was a significant difference for three out of the four key variables in CP (asthma attacks: $P=0.0092$; urgent medical examinations: $P=0.0216$; admission days: $P=0.0280$; working days lost: $P=0.0626$), and for the number of admission days in RP ($P=0.035$). A borderline value was found for the number of working days lost in RP ($P=0.0537$).

The cost of drugs increased significantly in both programs after enrolment (Table 4). The morbidity savings were \$1894.70 and \$1694.70 for CP and RP, respectively, from the perspective of society as a whole, and \$1349.50 and \$1301.80, respectively, from the perspective of health program policy makers (Table 5). The net cost-benefit was \$1181.50 for CP and \$1028.00 for RP, and the cost-benefit ratio per dollar spent was 1:2.66 for CP and 1:2.53 for RP, respectively, from the perspective of society (Table 6). The number of episodes prevented (outcome variables) and the cost per unit of effect are summarized in Table 7. One day of admission prevented had a cost of \$110.20 and \$94.10, respectively, for CP and RP.

The incremental cost-effectiveness ratio was calculated for three out of the four variables, with a better outcome in the more expensive program (CP): asthma attacks=\$11.60; urgent medical examinations=\$34.40; and working days lost=\$21.70. Sensitivity analysis revealed better results for RP both when lower values of CI (savings: CP=\$1164.30; RP=\$1417.90; cost-benefit: CP=\$451.10; RP=\$748.10; cost-benefit ratio per dollar spent: CP=1:1.63, RP=1:2.1) and when upper values of CI (savings: CP=\$2102.60; RP=\$2138.20; cost-benefit: CP=\$1389.40; RP=\$1468.40; cost-benefit ratio per dollar spent: CP=1:2.95, RP=1:3.19) were applied to the key variables.

Table 3. Medical outcomes of complete and reduced program, during years before and after enrolment

Program	Complete		Reduced		P value
	Mean	Median	Mean	Median	
Year before					
No. of asthma attacks	8.40	7.5	7.84	5	> 0.05
No. of urgent medical examinations	1.66	0.5	1.87	1	> 0.05
No. of admission days	6.59	0	7.24	8	> 0.05
No. of working days lost	9.4	0	10.4	7	> 0.05
Year after					
No. of asthma attacks	4.72 ^a	3	7.91	5	> 0.05
No. of urgent medical examinations	0.72 ^a	0	2.18	1	< 0.05
No. of admission days	0.12 ^a	0	0.12 ^a	0	> 0.05
No. of working days lost	2.1	0	5.1	0	> 0.05

^aSignificant difference between year after vs year before enrolment.

Table 4. Cost of drugs used by patients following complete and reduced programs in years before and after enrolment

Program	Complete \$	Reduced \$	P value
Year before	254.8 ± 294.8	206.3 ± 182.1	> 0.05
Year after	528.6 ± 355.4	631.8 ± 470.9	> 0.05
P value	< 0.001	< 0.001	

Table 5. Calculation of morbidity cost before and after enrolment

Program	Complete \$	Reduced \$
Year before		
Urgent medical examinations	1.66 × 44 = 73	1.87 × 44 = 82.3
Admission days	6.59 × 244.5 = 1611.3	7.24 × 244.5 = 1770.2
Working days lost	9.37 × 75 = 702.7	10.38 × 75 = 778.5
Drug cost	254.8	206.3
Total	2641.8	2837.3
Year after		
Urgent medical examinations	0.72 × 44 = 31.7	2.18 × 44 = 95.9
Admission days	0.12 × 244.5 = 29.3	0.12 × 244.5 = 29.3
Working days lost	2.1 × 75 = 157.5	5.1 × 75 = 382.5
Drug cost	528.6	631.8
Total	747.1	1139.5

Table 6. Calculation of morbidity savings, cost-benefit, and cost-benefit ratio per dollar spent by program (1 = perspective of society as whole; 2 = perspective of paying bodies)

Variable		Program	
		Complete \$	Reduced \$
Morbidity savings	1	2641.8 - 747.13 = 1894.7	2837.3 - 1139.5 = 1697.8
	2	1939.1 - 589.6 = 1349.5	2058.8 - 757.0 = 1301.8
Cost-benefit	1	1894.7 - 713.2 = 1181.5	1697.8 - 669.8 = 1028
	2	1349.5 - 713.2 = 636.3	1301.8 - 669.8 = 632
Cost-benefit ratio	1	713.2/1894.7 = 1:2.66	669.8/1697.8 = 1:2.53
	2	713.2/1349.5 = 1:1.89	669.8/1301.8 = 1:1.94

Table 7. Number of episodes prevented and cost per unit of effect for outcome variables of two programs. In case of negative value of number of episodes prevented*, total program cost was considered

Variable	Program	
	Complete	Reduced
No. of episodes prevented		
Asthma attacks	3.68	-0.07*
Urgent medical examinations	0.94	-0.32*
Admission days	6.47	7.12
Working days lost	7.3	5.3
Cost by unit of effect	\$	\$
Asthma attacks	193.8	669.84*
Urgent medical examinations	758.7	669.84*
Admission days	110.2	94.01
Working days lost	97.7	126.4

Discussion

Both the complete and the reduced programs produced a significant improvement in the main outcome variable (admission days); CP was slightly more expensive than RP and produced slightly higher savings, considered from the perspective of society as a whole (\$196.90 more) and from that of health policy makers (\$47.70 more). The net cost-benefit of CP was \$153.50 higher than that of RP from the perspective of society, and \$4.30 higher than RP from the viewpoint of health policy makers.

According to the costs applied in the model, the most relevant outcome variables from an economic point of view are the number of admission days and the number of working days lost (Table 6). While CP had a good effect on the number of asthma attacks, urgent medical examinations, and working days lost, it was slightly less effective on the economically most important outcome variable (admission days). RP, on the contrary, did not result in a reduction of number of asthma attacks or urgent medical examinations (-0.07 and -0.32, respectively).

Our data on the year before enrolment were, as in other studies (1, 14), collected by questionnaire. The questionnaire was counterchecked by medical records to verify directly three of the four variables (number of urgent medical examinations, days of admission, and working days lost), and the drug costs. This procedure helped us to evaluate the plausibility of the number of asthma attacks declared in the questionnaire. However, any bias was equally distributed between group and control patients. In fact, there were no differences between CP and RP for the most common confounders (age, sex, smoking habits, FEV₁, etc.). It has been suggested that written questionnaires may overestimate compliance by as much as 30% (19), possibly contributing to overestimation of the financial cost of drugs in the year before enrolment. Consequently, the true difference in cost between CP and RP before vs after enrolment was probably higher. Although the retrospective design used to determine baseline utilization and costs may have inflated absolute differences in costs between CP and RP, this bias was distributed similarly in both programs. Moreover, the number of asthma attacks in the period before enrolment may also have been underestimated due to imprecise recall (1, 19). The resulting possible overestimation of the total savings was counterbalanced by the underestimation of the real cost of the results of the programs. In addition, the cost of 1 day of hospital admission, as derived from national statistics (16, 17), is averaged on hospitals of different levels. For example, for high-level centers, the "per diem" refund in 1994 was 23.4% higher than the average estimated refund of \$244.50.

Our results are consistent with two other reports of a reduction of hospital days per patient per year from 6 to 1 (14) and from 14 to 7 (20). In our study, the number of days of admission prevented was 6.47 for CP and 7.12 for RP. This result might be due to the small sample size. Our sample size was selected in view of the results of a pilot study that included a biologic and an economic variable (13). The estimated 85% power may be lower for this variable; consequently, this result might be not sufficiently protected from a second-type error. In addition, the final sample size showed an 18.8% dropout rate.

Both our programs resulted in financial savings. From the perspective of society as a whole, the net cost-benefits were \$1681.50 and \$1028.00, respectively, for CP and RP. From the perspective of the paying bodies, the net cost-benefits were still relevant (\$636.30 and \$632.00, respectively). The difference between the cost-benefits of the two programs under different perspectives may vary, modifying the criterion used in estimating the financial value

of indirect costs. The decision to analyze data of only employed patients probably contributed to the underestimation of the real savings and benefits produced by both programs. If temporary absence from work leads to losses or delays in services provided (3, 21), probably the loss of other activities (those of housekeepers) and of a kind of investment (students) also represents an economic burden on society (3). In fact, other authors included those activities in their analyses and estimated their annual value in financial terms (2). In addition, the use of the average gross salary could result in an underestimation of the loss of productivity (1).

The results of our study are noteworthy because interventions that produce medical benefits usually cause relevant additional monetary costs. If we consider that in the last 2 years the Italian lira has lost about 30% of its purchasing power and that the cost of both programs was influenced by equipment paid for in foreign currency (e.g., the spirometer was purchased from Jaeger, Germany), our results are consistent with those of other studies. For example, Mayo et al. (22) calculated a reduction in cost of \$1935.00 per patient per year, and Trautner et al. (1) a net benefit of DM 2350 and 2550, respectively, in the second and third year after enrolment, while, in the first year, program costs (the program was done on an inpatient basis) outweighed savings. Although it appears that the costs for a patient with asthma can amount to a substantial portion of a family's gross annual household income (2, 23), few studies have examined the question from the stance of the individual patient. From the determination of drug costs by our study, we calculate that about 1/30 of the total income of a patient affected by asthma might be used to purchase drugs in Italy. Considering the relevant savings the paying bodies might obtain with such programs, we underline the importance of distributing antiasthma drugs free of charge.

Among the limitations of the few economic studies available on this topic are approximation of estimates, use of point estimates, and difficulty in determining standard errors (2). We evaluated the cost of examinations (determining the program cost) by taking into account all the relevant items (inflation-adjusted discount rate, allotment of general expenses, number of tests performed with the equipment, etc.); moreover, staff cost was calculated from official salaries. Therefore, our economic estimates might be of help in planning and evaluating antiasthma activities from the two perspectives considered.

In conclusion, CP produced results similar to RP. The costs and economic outcomes of both programs were analyzed before cost-benefit and cost-effectiveness analysis. Both analyses confirmed that

RP improves the outcome variables and determines relevant savings. Although sensitivity analysis showed the results not to be consistent over a broad range of variations in the values of the key variables, the difference between the economic results of both programs was small when the outcome variables were tested at their upper and lower 95% CI. In addition, it is possible that absolute differences in costs between CP and RP might have been artificially inflated by the retrospective analysis used to determine baseline costs.

Since both programs were similarly designed as to diagnosis, treatment, and follow-up of patients, and produced similar outcomes, we agree that the key features of an asthma program should be proper treatment and regular supervision of asthmatics (24). The complete program improved patients' welfare and determined consistent financial savings, proving to be slightly more economically beneficial than the reduced program.

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