Improvement in asthma control and reduction in medical resource use following treatment with montelukast (PRAACTICAL Study) – Results from Poland

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Poprawa kontroli astmy i zmniejszenie zużycia środków opieki medycznej u chorych leczonych montelukastem (badanie PRAACTICAL) – wyniki uzyskane w Polsce

CEL: Ocena długo- i krótkookresowej kontroli astmy u chorych z niedostatecznie kontrolowaną, łagodną lub umiarkowaną astmą przewlekłą i sezonowym alergicznym nieżytem nosa (SAR), wymagających dołączenia montelukastu.
METODA: Chorzy leczeni wziewnymi kortykosteroidami bez/z beta-mimetykami, którzy rozpoczęli jednoczesne przyjmowanie montelukastu zostali włączeni do wieloośrodkowego, 12-miesięcznego, retrospektywnego badania kohortowego z analizą pre-post, tj. przed i po wdrożeniu terapii montelukastem. Długookresową kontrolę astmy zdefiniowano jako ataki astmy (hospitalizacja, nagłe wizyty w izbie przyjęć (ER) lub stosowanie doustnych glikokortykosteroidów); krótkookresową kontrolę astmy mierzono stopniem zużycia krótkodziałających beta-mimetyków (SABA).
WYNIKI: Dane 334 chorych na astmę z SAR dostarczyło 33 lekarzy. Stwierdzono znamienne zmniejszenie odsetka chorych z atakami astmy (z 28% do 9%, p<0,001), wymagających nagłej pomocy w ER (z 14% do 3%, p<0,001), hospitalizacji (z 3% do 0,6%, p=0,021) lub przyjmowania SABA (z 87% do 79%, p<0,01). Średnia ilość wizyt w ER i hospitalizacji zmniejszyła się odpowiednio o 77% oraz 67%, p<0,01. Po dołączeniu montelukastu zaobserwowano także istotne zmniejszenie odsetka chorych przyjmujących doustne kortykosteroidy, antybiotyki i leki przeciwalergiczne (w każdym przypadku p<0,01).
WNIOSKI: Dołączenie terapii montelukastem u pacjentów z astmą i SAR znamiennie zwiększyło długo- i krótkookresową kontrolę astmy, powodując zmniejszenie zużycia środków opieki medycznej.

Objective:

To evaluate long- and short-term asthma control in inadequately controlled patients with mild/moderate persistent asthma and seasonal allergic rhinitis (SAR) requiring addition of montelukast as part of routine care.

Methods:

Patients on inhaled corticosteroid (alone or in combination with beta-agonists), who started concomitant montelukast between Jan-1999 and Dec-2002 were included in a multicenter, 12-month, pre-post retrospective cohort study. Asthma attacks (hospitalization, emergency room (ER) visit or oral corticosteroid use) and short-acting-beta-agonists (SABA) use were defined as long- and short-term control respectively. 33 physicians provided data on 334 asthmatics with SAR in Poland [average age 31.7, 58% female, 58% mild, 42% moderate persistent asthma].

Results:

A significant decrease was found in proportion of patients experiencing an asthma attack (28% to 9%, p<0.001), ER visit (14% to 3%, p<0.001), hospitalization (3% to 0.6%, p=0.021) or requiring SABA (87% to 79%, p<0.01). Mean number of ER visits and hospitalizations declined by 77% [from 30 patients)] and by 67% [from 6 to 2 (per 100 patients)] respectively, both p<0.01. Significant decline in proportion of patients using oral corticosteroids, antibiotics and allergy medications was also observed (all p<0.01) post montelukast initiation.

DRUGS AND RESOURCE USE IN ASTHMA AND AR - SUMMARY

Main results related to severity and control of asthma among patients participating in the study are described as a summary.
Data at the last row ("Combined"), include patients requiring anyone of the previous resources. Those requiring more than one are not repeated.

1. The proportion of patients using **SABA** was significantly lower the year after initiating montelukast
2. The proportion of patients using **oral corticosteroids** was significantly lower the year after initiating montelukast
3. The proportion of patients requiring **unscheduled, telephonic or at home medical visits** to the GP and specialist was significantly lower the year after initiating montelukast
4. The proportion of patients requiring **emergency visits** was significantly lower the year after initiating montelukast.
5. The proportion of patients requiring **hospitalization** was significantly lower the year after initiating montelukast
6. The proportion of patients requiring the **use of any resources combined (except medical visits)** was significantly lower the year after initiating montelukast
7. The proportion of patients requiring the **use of any resources combined (except medical visits and including SABA use)** was significantly lower the year after initiating montelukast

Medical Resource Use one year before and one year after initiation of Montelukast. **N=334**

Oral corticosteroids use, n (%)		
	Pre	51 (15.3%)
	Post	18 (5.4%)
p-value		<0.001
Unscheduled medical visits, n (%)		
	Pre	183 (54.8%)
	Post	112 (33.5%)
p-value		<0.001
Emergency visits, n (%)		
	Pre	48 (14.4%)
	Post	9 (2.7%)
p-value		<0.001
Hospitalizations, n (%)		
	Pre	10 (3.0%)
	Post	2 (0.6%)
p-value		0.021
Combined(OCS+emergency+hospitalization), n (%)		
	Pre	93 (27.8%)
	Post	29 (8.7%)
p-value		<0.001
SABA (%)	Pre	289 (86.5%)
	Post	264 (79.0%)
p-value		<0.001
Combined(OCS+SABA+emergency+hospitalization), n (%)		
	Pre	297 (88.9%)
	Post	270 (80.8%)
p-value		<0.001

**: p<0.01 comparison pre-post*
***: p<0.05 comparison pre-post*

DRUG AND RESOURCE USE UNIT COSTS

The Polish Health Care system started to be modified in 1990 and is still under construction, this means not always is easy to obtain unit cost data.
Source data for hospitalization costs were based on information showed on the official National Health Found (NFZ) web site - www.nfz.gov.pl., however hospitalization costs starting from 1999 to 2002 years were diversified for hospitals in different parts of Poland, so sometimes no data were found.
Costs of visits to specialist doctors are not easy to obtain as well. Data from some web sites of non public health care providers (eg www.alfa-lek.com.pl; www.republika.pl/jo_sz23/fundacja/ceny) and from numerous phone calls have been obtained.
Prices for specialist visits and costs of hospitalization referred to 2004 year.
Cost of medication is catalogued and comes from the "Pharmindex" 2000/2001 edition.

Unit cost data on resource use

Medical Resources	**Unit costs (€)** [a]
Concomitant medication[b]	
SABA	0-0.4
ICS	0-1.62
LABA	0.13-0.58
Montelukast	0.8
Oral corticosteroids	0-2.01
Outpatient visits	
to allergologist	18
to dermatologist	14
to family practice physician	14
to internist	18
to laryngologist	14
to pneumologist	18
Emergency room visits	22
Day in hospital	
in respiratory ward	50
in general ward	45
in ICU	400

[a] Adjusted to 2004 € by applying Harmonize Consumer Price Index.
[b] Minimum and maximum daily cost by drug class after assuming co-payments.

Number of Medical Visits,Consultations and Costs associated to Asthma one year before and one year after initiation of montelukast.

(0"values , those patients without use of resources, are NOT included)

N=334		**Medical visits,** mean (SD) [median]	**Consultations,** mean (SD) [median]	Costs associated to Asthma resource **€ mean,** (SD),[median]
General Practioner	Pre	6.6 (3.0) [6]	6.4 (3.2) [6]	14.6 (28.2) [0]
	Post	5.7 (2.9) [5] *	5.5 (3.0) [5] *	7.8 (22.2) [0]*
Allergologist	Pre	5.7 (2.6) [5]	3.6 (3.4) [4]	64.9 (61.8) [72.0]
	Post	5.4 (2.6) [5] **	3.4 (3.3) [3] **	60.9(59.6) [54.0] **
Pneumologist	Pre	6.0 (2.0) [6]	1.5 (2.8) [0]	26.8 (50.1) [0]
	Post	5.2 (2.4) [5] *	1.4 (2.6) [0] bl	24.8 (46.8) [0]**
ORL§	Pre	1.7 (0.8) [1]	0.1 (0.5) [0]	1.9 (7.1) [0]
	Post	1.3 (0.6) [1]	0.07 (0.3) [0]	1.0 (4.4) [0]*
Internal Medicine§	Pre	5.3 (2.2) [5.5]	0.09 (0.7) [0]	1.7 (13.6) [0]
	Post	4.8 (1.5) [5.5]	0.08 (0.7) [0]	1.6 (12.0) [0]
Cardiologist§	Pre	1.0 (-) [1]	0.003 (0.05) [0]	0.05 (1.0) [0]
	Post	3 (-) [3]	0.009 (0.2) [0]	0.2 (2.9) [0]
Dermatologist§	Pre	1.0 (0) [1]	0.02 (0.1) [0]	0.2 (1.9) [0]
	Post	1.0 (0) [1]	0.006 (0.08) [0]	0.08 (1.1) [0]
Oftalmologist§	Pre	-	0 (0) [0]	0 (0) [0]
	Post	-	0 (0) [0]	0 (0) [0]
Emergency Visits §, mean (SD) [median]	**Pre**	**1.5 (0.7) [1]**	**0.2 (0.6) [0]**	**4.7 (12.9) [0]**
	Post	**1 (0) [1]**	**0.03 (0.2) [0]** *	**0.6 (3.6) [0]***
Hospitalization	**Pre**		**0.04 (0.2) [0]**	**12.1 (104.5) [0]**
	Post		**0.006(0.08)[0]****	**2.1 (33.3) [0]****

§ Change not appropriate to evaluate statistically * p<0.01 comparison pre-post
** p<0.05 comparison pre-post bl p=0.059

Costs associated to Asthma treatment prescribed one year before and one year after initiation of montelukast

Drug Use – Asthma (€ mean, (SD), [median])		N=334 **Poland**
Inhaled corticosteroids	Pre	106.6 (121.7) [83.6]
	Post	119.0 (119.4) [91.0]
SABA	Pre	11.7 (22.4) [2.3]
	Post	9.2 (21.2) [1.6]*
LABA	Pre	160.0 (197.4) [98.7]
	Post	166.5 (199.6) [114.7]
Oral corticosteroids	Pre	0.3 (1.3) [0]
	Post	0.3 (2.3) [0]*
Antibiotics	Pre	5.4 (26.0) [0]**
	Post	1.8 (7.9) [0]
Antihistaminics+ antiallergics (rino)	Pre	14.1 (26.6) [0]
	Post	12.2 (25.7) [0]
Other	Pre	22.1 (60.0) [0]
	Post	17.3 (58.1) [0]*

Conclusions:

The initiation of montelukast therapy in asthmatics with SAR significantly improved long- and short-term asthma control resulting in profound reduction in asthma-related resource use.