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ORIGINAL ARTICLE

Factors affecting ability to achieve asthma control in adult patients with moderate to severe persistent asthma

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*Department of Pediatrics, Los Angeles County+University of Southern California Medical Center, Los Angeles, CA, USA***Abstract**

Objective: Despite the use of optimal therapy and guidelines, the rate of asthma control is suboptimal in adult populations. Purpose of this study is to describe factors associated with ability to achieve well-controlled asthma over time for adult patients treated in a tertiary medical center-based asthma outpatient specialty clinic. **Methods:** Existing clinical data collected for 320 adult patients enrolled in a hospital-based outpatient asthma specialty clinic from July 1, 2003 through June 30, 2011 evaluated time to achieve well-controlled asthma and factors associated with well-controlled asthma such as adherence and lack of previous exacerbations. **Results:** Adherence to prescribed therapy ($p = 0.004$) and no previous asthma related ED visits ($p = 0.004$) were associated with well-controlled asthma for moderate persistent baseline. BMI on a continuous spectrum ($p = 0.120$) and the diagnosis of allergic rhinitis ($p = 0.769$) were not independently significant. Body-mass-index (BMI) in combination with adherence did influence ability to achieve well-controlled asthma ($p < 0.05$). Adherence ($p = 0.615$), allergic rhinitis ($p = 0.172$), BMI continuous scale ($p = 0.074$) and visit interval < 90 days ($p = 0.653$) were not independently associated with likelihood of achieving well-controlled asthma in severe persistent asthmatics. Significance of particular factors in combination (adherence, allergic rhinitis, sex, BMI) showed dependency on other variables in achieving well-controlled asthma. **Conclusions:** Different factors are associated with asthma control for different patient subpopulations. Adherence to standard therapy did not improve obese (BMI > 30) patients' ability to achieve asthma control. Female patients were less likely to obtain well-controlled asthma per unit increase of BMI. Multiple factors must be addressed to optimize attaining asthma control.

Keywords

Adult asthma, well-controlled asthma, adherence, obesity, BMI, severity

History

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Introduction

Asthma affects greater than 18 million adults in the United States [1]. Asthma prevalence, asthma related morbidity, mortality, and economic costs associated with asthma have sharply increased over the last 40 years [2]. Lack of asthma control contributes to significant morbidity and mortality in the United States [1,3]. Lack of proper asthma control is associated with poorer quality of life and higher costs relative to controlled asthma [4,5]. The 2007 economic burden of asthma was estimated to be \$56 billion in direct medical costs and loss of productivity [6].

Guidelines focus on asthma control as a therapeutic goal [7,8]. The primary goal of asthma management is to achieve and maintain clinical control. Despite the availability of new pharmacological options and novel combinations of existing drug therapies, the rate of asthma control is suboptimal [9,10]. In previous published studies we have found that various factors are associated with asthma control among pediatric

patients enrolled in a similar program. These include adherence to chronic medication, frequency of follow-up visits and understanding of the disease [11,12]. Other factors include allergic rhinitis and obesity. Inflammation initiated in the upper respiratory epithelium has been shown to induce lower airway inflammatory changes and treatment of the upper airway improves lung function in asthmatics [13,14]. Studies have examined links between obesity and asthma. Pathogenesis of obesity may involve a systemic inflammatory state thereby facilitating persistent lung inflammation [15–20]. The purpose of this study is to describe the time to achieve well-controlled asthma and factors associated with the ability to achieve control over time for adult patients with moderate to severe persistent asthma treated in a hospital-based asthma outpatient specialty clinic of a major tertiary academic center.

Methods**Study population**

This study evaluated clinical data for adult asthma patients treated in an asthma-specific disease management program in the hospital-based Allergy + Immunology Clinic (Los

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Angeles County + University of Southern California Medical Center, LAC + USC) from July 1, 2003 through June 30, 2011. This study was approved by the University of Southern California Institutional Review Board. Clinical data was collected prospectively at the visit level and recorded in an electronic health record, Asmatrax (Loran Clement, Los Angeles). Patient inclusion criteria included a minimum age of 18 years at initial visit, initial visit diagnosis of persistent asthma, and return for follow-up visit within 6 months of initial visit. Factors associated with the ability to achieve well-controlled asthma considered in the analyses included: age, gender, race, body mass index (BMI), allergic rhinitis (AR) diagnosis, controller therapy prescribed, adherence to controller therapy prescribed, season of visit, visit interval, and baseline asthma disease severity recorded. Asthma control status was determinable by National Heart, Lung, and Blood Institute (NHLBI)/National Education and Prevention Program (NAEPP) 2007 guidelines [8] using a minimum of three impairment components (defined as daytime symptoms, nighttime symptoms, interference with normal activities, short-acting B₂-agonist use, lung function testing) and a risk component (defined as interval steroid burst).

Asthma control and initial asthma severity

Asthma control is defined as Well-Controlled, Not Well-Controlled, or Very Poorly Controlled (2007 NAEPP guidelines) [8] based on components of impairment and risk recorded within AsmaTrax. Impairment symptoms (cough, wheeze, dyspnea, and/or chest tightness) were recorded as daytime symptoms and nighttime symptoms during the preceding 2–4 weeks before the visit. Daytime symptom occurrence was recorded as none, ≤ 2 times/week, > 2 times/week but not daily, daily, or multiple times per day. Nighttime symptom occurrence was recorded as none, ≤ 2 nights/month, 3–4 nights/month, > 5 nights/month, or nightly. Exercise symptoms (proxy of impairment of daily activities) were recorded as none, usually, sometimes, or always. The recall period was over the preceding 2 weeks.

Impairment also included interference with normal activities, asthma-related ED visits, hospitalizations, and school days missed during the visit interval. Lung function testing was performed according to American Thoracic Society recommendations and applied per 2007 guidelines by age [21]. Lung function results were incorporated into control assessment when available. Risk was defined as interval systemic steroid burst.

Initial asthma severity was classified according to 2007 NAEPP guidelines [8] using impairment and risk domains. Significant number of patients were already on asthma controllers upon referral and first visit. These patients had their initial asthma severity classified by the referring provider. Many patients classified with severe persistent asthma by their referring providers upon first visit to our service were on step 5 or above of therapy.

Clinical data was collected before and after the implementation of the 2007 NAEPP guidelines. Symptom frequency, short acting B₂ agonist use, oral steroid burst and lung function testing were collected in the same fashion in the same EHR pre and post 2007. Therefore, clinical criteria to assess asthma severity

and control using the 2007 asthma guidelines were the same before and after 2007.

Body mass index was calculated using body weight and height which were recorded at every visit [15], medications prescribed were recorded in the AsmaTrax EHR for analysis, baseline asthma severity was rated using symptoms from the first visit using 2007 NAEPP asthma guidelines and adherence to controller therapy was rated by the specialist provider based upon patient history and recall.

Patients were asked by the provider at each visit whether they were adherent to controller medication during the previous 2 weeks. This information in combination with remaining medication controller medication refills when medications were brought to the clinic visit was used to determine if patients were adherent or non-adherent and entered into the EHR. We did not record number of days adherent or adherence to multiple controllers if more than one was prescribed during the previous visit.

Statistics

A multivariable analysis was performed using Cox regression analyses (Proc PHREG in SAS), generalized estimating equations (Proc GENMOD in SAS) [22]. Analysis examined time to achieve clinical control of asthma (survival analysis using cox-regression procedures). Initial analysis examined the influence of each factor on time to event to establish a baseline measure of association and significance. Age was explored on a continuous scale to assess potential linear quadratic relationship and on categorical scale with consideration to age distribution in study population. A stratified analytic approach was applied to adjust for baseline disease severity. The analysis extended to influence of co-morbid conditions with adjustment for other potential confounding factors (fully adjusted model).

The analysis examined two-way interaction effects and retained those found to be significant in fully adjusted model. All two-way interaction effects between factors considered in analysis were examined in a stepwise manner in the fully adjusted model and those found to be significant retained. The analysis described the relationship of co-morbid conditions on time to achieve control within each baseline severity group (mild persistent, moderate persistent, severe persistent). Interactions between other independent variables such as obesity and medication adherence were also examined for their combined impact upon asthma control.

Results

Table 1 describes the characteristics of the study population. Two hundred and sixty-three patients (out of 320 with asthma diagnosis) had persistent baseline asthma at the time of enrollment and were included in this study (57 patients were excluded from the analysis because of baseline intermittent asthma severity). The analysis included 937 total visits (263 initial visits and 674 follow-up visits) with a median visit interval of 63 days (Interquartile Range, IQR: 39, 98). Demographics for age and race were similar for all baseline severity groups. The majority of patients were characterized as having baseline severe persistent disease (53.6%) with 35.7% of patients having moderate persistent baseline disease. 10.7% of remaining asthma patients were mild persistent and were not analyzed. There

Table 1. Description of adult asthma patients (age ≥ 18 years) treated at LAC + USC from July 1, 2003–June 30, 2011 with return for follow-up care within 6 months of first visit.

Categorical factors: N (valid %)	
Continuous factors: mean (StD) N = 263	
Age, years, mean (StD) [range]	46.5 (12.3)
Female	184 (71.0%)
Race:	
Hispanic	143 (54.4%)
Caucasian	31 (11.8%)
African-American	17 (6.5%)
Other	14 (5.3%)
Unknown/Missing	58 (22.1%)
Baseline asthma severity:	
Intermittent	0
Mild Persistent	28 (10.6%)
Moderate Persistent	94 (35.7%)
Severe Persistent	141 (53.6%)
Controller Naïve at baseline ^a	129 (49.0%)
Annual Morbidity Prior to Entry ^b	
ED visits (any)	89 (33.8%)
Hospitalizations (any)	30 (11.4%)
Co-morbidities:	
Allergic Rhinitis ^c	189 (73.0%)
COPD ^d	21 (8.0%)
BMI at baseline, mean (StD):	30.2 (7.0)
Underweight (BMI <18.5)	9 (3.6%)
Normal (BMI 18.5–24)	35 (14.1%)
Overweight (BMI 25–29)	77 (30.9%)
Obese (BMI ≥30)	128 (51.4%)
Total number(N) visits considered	Persistent N = 674
in analyses:	follow-up visits (+263 initial)
Median visit interval [IQR]	63 d [39,98]
<90 days	420 (62.3%)
90–181 days	227 (33.7%)
≥182 days	27 (4.0%)

^aController naïve at baseline defined as (off therapy or non-adherent).

^bLifetime experience normalized based on duration of disease, i.e. annual average in patients Dx > 1 year ago and actual past year experience in recently diagnosed cases.

^cIn 287 patients, allergic rhinitis status known at baseline visits; in 31 patients' allergic rhinitis detected within 365 days of entry; in 5 patients, allergic rhinitis status not determinable.

^dEvaluated across first 365 days of entry (an additional 7 patients were diagnosed after one year of participation – not included in positive group (numerator)). Then 15 of 23 positive for COPD had severe persistent baseline disease severity.

were no patients with intermittent asthma. A large proportion of patients were either overweight (30.9%) or obese (51.4%). In all 73.0% of patients had a co-morbid diagnosis of AR. Mean time to achieving asthma control in patients with moderate and severe persistent asthma were 4 and 6 visits, respectively (data not shown).

Factors affecting ability to achieve asthma control in moderate persistent patients. Table 2 describes factors associated with the likelihood of achieving well-controlled asthma in any follow-up visit for patients with moderate persistent baseline severity. Factors associated with well-controlled asthma include adherence to prescribed therapy ($p = 0.004$) and absence of asthma related ED visits ($p = 0.004$), unadjusted for other variables. BMI on a continuous spectrum and the diagnosis of allergic rhinitis were not significant factors to time to achieve well-controlled asthma ($p = 0.120$ and $p = 0.769$, respectively). However, multi-variant analysis demonstrated that adherence was associated with ability to achieve asthma

Table 2. Time to achieve well-controlled asthma in patients with moderate persistent baseline asthma disease.

Single Factors Significant for Moderate Persistent Baseline (N = 94)	
Adherence (Y vs. N):	$p = 0.004^{\dagger}$
ER visits baseline (Any vs. None):	$p = 0.004$
BMI entry (continuous):	$p = 0.120^{\dagger}$
Allergic Rhinitis Dx (+ vs. -):	$p = 0.769^{\dagger}$
[[†] Factor's relationship to time to achieve control depends on level of other variable (significant interaction effects)]:	
BMI entry* Adherence:	$p = 0.009$
Multi-factorial Influence of Factors Significant for Moderate Persistent Baseline (N = 94):	
Adherent vs. Non-Adherent when:	
BMI = 20,	HR* = 205.21 (6.46,6521.14), $p = 0.003$
BMI = 25,	HR = 59.83 (4.34,824.56), $p = 0.002$
BMI = 30,	HR = 17.44 (2.69,113.07), $p = 0.003$
BMI = 35,	HR = 5.09 (1.33,19.44), $p = 0.017$
BMI = 36,	HR = 3.97 (1.10,14.42), $p = 0.036$
BMI = 37,	HR = 3.11 (0.88,10.97), $p = 0.078$
BMI = 40,	HR = 1.48 (0.39,5.66), $p = 0.565$
BMI (per one unit increase) in:	
Patients Adherent,	HR = 0.90 (0.84,0.96), $p = .001$
Patients Non-Adherent,	HR = 1.14 (0.96,1.37), $p = 0.120$
ED visits _baseline (any vs. none):	HR = 0.36 (0.18,0.72), $p = 0.004$

*Hazard ratio based on Cox regression analyzes compares hazard rate of event (ability to achieve well-controlled asthma) in the respective category to the reference level with a per one-unit increase in the value for continuous factors. For patients with moderate persistent baseline, adherence to prescribed therapy and any previous emergency department visit (compared to none).

control in relationship to patient's BMI ($p < 0.5$). Adherence was not categorized. It was rated as adherent or not adherent to therapy based upon patient history and recall. Lower BMI values and adherence were associated with increased likelihood of achieving control while patients with high BMI had no significant change in ability to achieve asthma control whether they were adherent or not to therapy.

Factors affecting ability to achieve asthma control in severe persistent patients. Table 3 describes factors associated with the likelihood of achieving well-controlled asthma for patients with severe persistent baseline severity. Single factors not significantly associated with the likelihood of achieving well-controlled asthma in this group included adherence ($p = 0.615$), allergic rhinitis ($p = 0.172$), BMI continuous scale ($p = 0.074$) and visit interval <90 days ($p = 0.653$).

In the adjusted analysis, significance of particular factors showed dependency on other variables. Adherence was significant to likelihood of achieving control in patients with allergic rhinitis [Adherence + vs. -: HR = 7.51 (2.42,23.3), $p = .001$]. However, positive effect of adherence diminished when visit intervals extended beyond 90 days in patients with allergic rhinitis to a greater extent than those without allergic rhinitis [HR = 0.05 (0.01,0.29), $p = 0.001$]. In female patients, a one unit increase in BMI corresponded to a 79% reduced likelihood of achieving control in any subsequent visit interval ([HR = 0.21 (0.07,0.63), $p < 0.05$]). This trend was not observed in male patients; however, adult males were significantly less likely to achieve control in any subsequent

Table 3. Time to achieve well-controlled asthma in patients with severe persistent baseline asthma disease.

Single Factors Significant for Severe Persistent Baseline (<i>N</i> = 144)	
Adherence (Y vs. N):	<i>p</i> = .615 [□]
Controller Naïve at baseline (Y vs. N),	<i>p</i> = 0.005 [□]
BMI_entry (continuous),	<i>p</i> = 0.074 [□]
Allergic Rhinitis Dx (+ vs. –),	<i>p</i> = 0.172 [□]
Steroid burst required at baseline (Y vs. N),	<i>p</i> = 0.030 [□]
Age at baseline (continuous),	<i>p</i> < 0.001
Gender (M vs. F),	<i>p</i> = 0.040 [□]
Visit interval (VI) <90 d (Y vs. N),	<i>p</i> = 0.653 [□]
[[□] Factor's relationship to time to achieve control depends on level of other variable(s)]:	
Controller Naïve Baseline*Gender,	<i>p</i> = 0.008
Steroid Burst at Baseline*Gender,	<i>p</i> = 0.051~
BMI entry*Gender,	<i>p</i> = 0.011
Allergic Rhinitis Dx*Adherence,	<i>p</i> = 0.008
Allergic Rhinitis Dx*Visit interval <90 d,	<i>p</i> = 0.014
Multi-factorial Influence of Factors Significant for Severe Persistent (<i>N</i> = 144)	
Adherent vs. Non-Adherent in:	
Patients + Allergic Rhinitis,	HR = 7.51 (2.42,23.3), <i>p</i> = 0.001
Patients – Allergic Rhinitis,	HR = 0.71 (0.19,2.67), <i>p</i> = 0.615
Controller Naïve at Baseline (Y vs. N) in:	
Male Patients,	HR = 0.21 (0.07,0.63), <i>p</i> = 0.005
Female Patients,	HR = 1.21 (0.62,2.37), <i>p</i> = 0.572
Steroid Burst Required at Baseline (Y vs. N) in:	
Male Patients,	HR = 0.19 (0.04,0.85), <i>p</i> = 0.030
Female Patients,	HR = 0.97 (0.49,1.90), <i>p</i> = 0.919
BMI (per one-unit increase) in:	
Male Patients,	HR = 1.15 (0.99,1.35), <i>p</i> = 0.074
Female Patients,	HR = 0.93 (0.89,0.98), <i>p</i> = 0.004
Allergic Rhinitis (+ vs –) in:	
Pts. Adherent and <90 d VI,	HR = 0.27 (0.04,1.76), <i>p</i> = 0.172
Pts. Non-Adherent and <90 d VI,	HR = 2.88 (0.96,8.63), <i>p</i> = 0.059
Pts. Adherent and ≥90 d VI,	HR = 0.05 (0.01,0.29), <i>p</i> = 0.001
Pts. Non-Adherent & ≥90 d VI,	HR = 0.56 (0.25,1.27), <i>p</i> = 0.166
Age at baseline (per one YR increase):	HR = 0.94 (0.92,0.97), <i>p</i> < 0.001

Hazard ratio based on Cox regression analyzes compares hazard rate of event (ability to achieve well-controlled asthma) in the respective category to the reference level with a per one unit increase in the value for continuous factors. For patients with moderate persistent baseline, adherence to prescribed therapy and any previous emergency department visit (compared to none).

visit interval when steroid burst required at the baseline visit [HR = 0.21 (0.07,0.63), *p* = 0.005]. This effect was not observed in female patients.

Discussion

This is a large retrospective study examining factors associated with asthma control in adult patients with persistent disease. Just over half of the study population described is Hispanic; thus, study results may not be typical of all ethnicities. The large proportion of patients with severe persistent baseline compared to mild or moderate is likely due to the nature of the clinic whereby the more severe patients are referred for specialty evaluation. Over 80% of the patient population was either obese or overweight. This observation is becoming more prevalent throughout the general US and world population. The prevalence of obesity and asthma has increased over the past decade [16]. In this current study we demonstrate that ability to achieve asthma control was not independently associated with adherence, allergic rhinitis, and BMI. Adherence to therapy in combination with absence of previous asthma related ED visit was associated with increased asthma control. BMI measured on a continuous scale in combination to adherence had no effect on asthma control. However overweight patients with lower

BMI in conjunction with adherence had significantly improved ability to achieve asthma control.

BMI on a continuous scale independently was not significant in time to achieve well-controlled asthma in either moderate or severe asthma patients. Previous reports have found an increased odds ratio for asthma prevalence to be between 1.6 and 3.0 in obese patients [16,17]. In our study, we found when obesity was evaluated in combination with adherence an interaction effect existed in moderate patients' abilities to achieve well-controlled asthma. Patients with larger BMI tended to have the inability to obtain well-controlled asthma even when compliant with therapy. Obese patients may have perception of dyspnea and chest tightness due to being overweight and not due to asthma symptoms.

Adherence to standard therapy did not improve obese patients' ability to achieve asthma control. These results suggest that more obese patients may be less responsive to conventional forms of therapy. This is congruent with other studies which have shown that, obese asthma patients are often difficult to control and have variable responses to conventional therapies. It has been hypothesized that there is presence of systemic inflammation in obese patients which may contribute towards resistance to corticosteroid therapy [18–20]. Further

investigation is warranted to identify which therapies may be of increased benefit in obese patients with asthma to better control asthma symptoms.

For our study population with severe persistent baseline therapy, female patients were less likely to obtain well-controlled asthma per unit increase of BMI. This has also been found in recently described female asthma phenotype who have poor lung function, high asthma related comorbidities, and decreased response to short-acting beta agonist [23,24]. Younger age at the time of initial asthma diagnosis and being on therapy without requirement of a steroid burst at baseline in male patients were also significant factors associated with improved ability to achieve control. Difficulties in treating older adults have previously been reported and include difficulties with inhaler use, decreased responsiveness to short-acting beta agonist therapy, and difficulty with understanding asthma treatment plans [25–27].

Adherence to prescribed therapy was an independent factor significantly associated with the ability to achieve well-controlled asthma for patients with moderate persistent severity but not severe persistent baseline asthma severity. This latter group of patients may represent what is often referred to as brittle or difficult to control asthma [28]. Patients who benefited most from adherence were those with co-morbid condition of allergic rhinitis. In our disease management program, upper airway disease is evaluated and managed in the same ‘step-up/step-down’ manner that asthma guidelines recommend for asthma management [8] to treat upper and lower airway disease pathology as a whole [29].

ED visits and systemic steroid burst requirements (for control of asthma exacerbation) are known risk factors associated with increased risk for asthma exacerbation [8,9]. In our study, these risk markers were associated with lower likelihood of achieving well-controlled asthma with each subsequent visit. For moderate persistent patients, a previous ED visit for asthma symptoms was associated with less likelihood of achieving well-controlled asthma. The guidelines state these elements of risk are associated with worse severity by definition [8,9]; however, we report these elements are also associated with less likelihood of attaining well-controlled asthma in any subsequent visit interval.

Several limitations exist in this study. The symptoms reported by patients are subject to recall bias; however, this bias was minimized by using a 2–4-week recall period for symptom reporting. This study represents a real-world treatment setting. Spirometry was included in control assessment for a small proportion of patients. Spirometry was performed routinely at every visit during the last 4 years of our clinic but was only performed approximately every 6 months in the preceding years. Therefore, we did not have lung function tests at every visit to use these criteria to assess control in all patients. They were however performed for all patients during the initial visit to assess asthma severity. The percentage of patients who achieved well-controlled asthma could be slightly overestimated by patients who are poor perceivers of disease and under report symptoms [30]. Also, adherence was subjectively estimated by the providers based on a combination of patient reporting of controller use and remaining medication refills when medications were brought to the clinic visit. Studies

have shown that patients often over report medication use to providers [31].

However, in our previous studies in our pediatric population, we have shown that provider assessment of adherence often correlates with guidelines-defined asthma control [12]. Some patients were already taking controller agents at their first visit with our service and their asthma severity was rated by the referring provider. Although referring providers to our service are receive continuous updates on asthma diagnosis and treatment from our disease management outreach program there may be provider variability in asthma severity rating of these patients. We did not measure certain variables that could affect ability to control asthma in this adult population including smoking status, medications used for allergic rhinitis, control of allergic rhinitis and BMI fluctuations.

Environmental irritants such as tobacco smoking and secondhand exposure likely affects asthma control in adult asthma patients; unfortunately, we did not have a robust record of smoking history in our cohort for such analysis. Finally, this study was carried out over 8 years and in this period of time there were new developments in treatment strategies and medications such as newer inhaled steroids and combination therapy. The change of treatment might affect results of this study.

Asthma related health burden continues to be significant, especially among non-Caucasians in inner-city urban areas [5]. Lack of proper asthma control is associated with poorer quality of life, work related productivity loss, substantial clinical burden, higher costs related to greater proportion of asthma medications prescribed, emergency room visits, hospitalizations and death relative to controlled asthma [32]. The ability to review patterns of asthma control and identify factors that contribute to asthma exacerbations/worsening asthma control is important for identifying implementation measures to reduce exacerbations and improve asthma [33]. The results of this study identify factors associated with ability and inability to achieve well-controlled asthma in the adult population.

Conclusion and key findings

Multiple factors either alone or in combination play roles in ability to achieve asthma control in adult patients. These include adherence to therapy, previous asthma related ED visits, and combination of adherence to medications and BMI. Attention should be paid towards these factors in treating asthma patients towards goal of asthma control.

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Declaration of interest

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