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Time Trends in Medication Use and Expenditures in Older Rheumatoid Arthritis Patients

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Abstract

Background—We sought to examine how expansions in insurance coverage of nonbiologic and biologic disease modifying anti-rheumatic drugs (DMARDs) impacted the access, costs and health status of older patients with rheumatoid arthritis.

Methods—We identified a nationally-representative sample of older adults with rheumatoid arthritis in the 2000–2006 Medicare Current Beneficiary Survey (unweighted n=1051). We examined changes in DMARD use, self-reported health status, functional status (activities of daily living [ADL]), and total costs and out-of-pocket costs for medical care and prescription drugs. Tests for time trends were conducted using weighted regressions.

Results—Between 2000 and 2006, the proportion of older adults with rheumatoid arthritis who received biologics tripled (4.6% vs. 13.2%, p=0.01), while the proportion of people that used a nonbiologic did not change. During the same period, the proportion of older rheumatoid arthritis patients rating their health as excellent/good significantly increased (43.0% in 2000 to 55.6% in 2006; p=0.015). Significant improvements occurred in activities of daily living measures of functional status. Total prescription drug costs (in 2006 US dollars) increased from \$2645 in 2000 to \$4685 in 2006, p=0.0001, while out-of-pocket prescription costs remained constant (\$842 in 2000 vs. \$832 in 2006; p=0.68). Total medical costs did not significantly increase (\$16563 in 2000 vs. \$19510 in 2006; p=0.07).

Conclusions—Receipt of biologics in older adults with rheumatoid arthritis increased over a period of time where insurance coverage was expanded without increasing patients' out-of-pocket

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costs. During this time period concurrent improvements in self-reported health status and functional status suggest improved arthritis care.

Keywords

Rheumatoid Arthritis; Disease Modifying Anti-Rheumatic Drugs (DMARD); Biologic Response Modifiers; Medication; Costs

Introduction

Treatment practices for rheumatoid arthritis have changed dramatically in the last ten years to promote earlier intervention and more aggressive use of disease modifying anti-rheumatic drugs (DMARDs).¹ Biologic agents such as adalimumab, etanercept, and infliximab as well as nonbiologic DMARDs have demonstrated substantial effectiveness in reducing disease activity, reducing joint erosions and improving quality of life of rheumatoid arthritis patients.¹⁻⁴ However, there is some limited evidence that older adults with rheumatoid arthritis are less likely to receive DMARDs than younger adults despite similar disease activity.⁵⁻⁹ Possible explanations include concerns regarding the safety of DMARDs in older adults with multiple comorbid conditions as well as age bias.¹⁰

Financial constraints may also influence the use of DMARDs, particularly biologic agents which are expensive. These agents are priced much higher than traditional DMARDs since they are costly to make, have unique mechanisms of action and are not available as a generic formulation. For example, the average cost of one administration of infliximab in 2006 was \$1,728.¹¹ Biologic agents can be either self-administered, such as etanercept and adalimumab, in which case they are designated as “specialty” drugs by most drug benefit plans and not covered by Medicare prior to 2004 or can be given intravenously like infliximab in doctor’s offices or infusion clinics and covered under insurers’ medical benefit (Medicare Part B).¹² Under Part B, Medicare paid drug manufacturers based on a drug’s average wholesale price resulting in higher prices than negotiated prices generally included in drug benefit plans.¹³ In 2003, the Medicare Modernization Act (MMA) established a temporary drug benefit for self-administered agents since prior to this no Medicare coverage existed. The goal of the MMA was to replace the need for infused drugs covered under Part B, including infliximab (called The Medicare Replacement Drug Demonstration program, which lasted from 2004 to 2005 and enrolled 14,929 low-income patients with rheumatoid arthritis). In 2006, Medicare offered prescription drug coverage (Part D) to Medicare beneficiaries and within 6 months 22.5 million seniors had enrolled in a Medicare Part D plan with 15.8 million having another source of drug coverage, and approximately 4.4 million (10 percent) with no coverage.¹⁴ For patients with rheumatoid arthritis, prescription drug plan provided access to oral and self-administered nonbiologic and biologic DMARDs. However, the specialty status of the biologic DMARDs required higher cost-sharing for rheumatoid arthritis patients enrolled in Part D plans.¹⁵

The objective of this study was to examine how expansions in insurance coverage influenced the use and costs of biologic and nonbiologic DMARDs in older patients with rheumatoid arthritis. We also tracked changes in self-reported health status and functional status. We examined these changes before and during the MMA demonstration project, and in the first year of Part D. We hypothesized that use of the DMARDs would increase, especially the most expensive biologics, as financial barriers were decreased.

Patients and Methods

Data Source

The Medicare Current Beneficiary Survey (MCBS) is a continuous face-to-face panel survey of a representative national sample of Medicare beneficiaries conducted by the Center for Medicare and Medicaid Services (CMS) in order to inform and evaluate health policies for Medicare beneficiaries.¹⁶ Since 1991, the MCBS has provided detailed longitudinal data on annual samples of Medicare beneficiaries with a current sample size of approximately 12,000 community-dwelling and institutionalized elderly and the disabled. The rich variety of measures includes demographic information, income, health status, functioning, health behaviors, health insurance coverage, drug coverage, health services utilization (including copayments, deductibles, and non-covered services), and access to medical care.

The sample for the MCBS is drawn from Medicare enrollment records according to a multi-stage sampling plan with oversampling of vulnerable subgroups such as the disabled and the oldest old. Respondents are selected in rotating 4-year panels with annual replenishments thus ensuring continued generalizability. The MCBS conducts a baseline interview between September and December covering demographics and household composition, as well as health insurance, health status, and health care utilization, including prescription drugs. This general interview is repeated yearly for the following 3 years. In addition, thrice-annual interviews collect detailed information on health care use and expenditures, with reviews of respondents' insurance statements and receipts. Each respondent keeps a record of insurance statements, receipts, and prescription bottles, in order to enhance the accuracy of data collection. Interviews are conducted in person with computer assistance resulting in very high response rates (initially ~85%). The typical MCBS interview lasts approximately one hour.

Study Sample

The study sample included Medicare beneficiaries with rheumatoid arthritis during the years 2000 through 2006. We identified patients as having rheumatoid arthritis if they had at least one of the following: 1) 2 or more ICD-9 diagnoses for rheumatoid arthritis (714.XX) based on claims data; 2) both self-reported rheumatoid arthritis and an ICD-9 diagnosis of rheumatoid arthritis; or 3) a dispensing of a nonbiologic or biologic DMARD (adalimumab, etanercept, hydroxychloroquine, infliximab, leflunomide, methotrexate, or sulfasalazine) and either self-reported of rheumatoid arthritis or an ICD-9 diagnosis of rheumatoid arthritis. We excluded institutional respondents as prescription drug expenditures are not captured for this population, and individuals with 3 or fewer months of entitlement to ensure a reliable time frame for estimation of annual medical care utilization. For individuals with 4 to 11 months of observation, we weighted their observation to reflect the partial year contribution (e.g. a person observed 4 months received a weight of 4/12). Given that each individual with rheumatoid arthritis could have provided a maximum of 4 years of data, the total number of individuals who participated in the study was 1,055. The unweighted sample size in each year ranged from 225 to 260.

Study variables

Our main study measure was receipt of one or more prescriptions of a DMARD each year of the study, which was based on self-reported medication use and prescription drug claims in Medicare Parts B and D. DMARD use was further classified into noncytotoxic (hydroxychloroquine and sulfasalazine), cytotoxic (leflunomide and methotrexate) and biologic (adalimumab, etanercept and infliximab).

Functional status was measured based on an assessment of activities of daily living, specifically responses about how much difficulty, if any, the respondents have with: 1) bathing or showering; 2) dressing; 3) eating; 4) getting into or out of a bed or a chair; 5) walking; and 6) using the toilet.¹⁷ For the purpose of our study, we used a dichotomous outcome of difficulty versus no difficulty with each activity of daily living. Persons who reported having any difficulty or not being able to perform any of the listed activities for reasons of health were categorized as having a limitation in the activity. The range of possible scores was 0 to 6 with a higher score reflecting a greater number of limitations. General health status is a global self-rating of health ranging from excellent to poor, which we dichotomized as excellent/very good/good and fair/poor.

Health care expenditures, measured through claims and review of receipts and insurance statements, included total medical costs, total prescription costs, DMARD-specific ambulatory prescription costs, and out of pocket costs. We inflated all cost values to 2006 prices using the consumer price index.¹⁸

Other covariates of interest included age, gender, race, residence (rural versus metropolitan), and comorbidity burden. Comorbidity burden was assessed based on a count of self-reported comorbid medical conditions (0, 1 – 2, and 3). We also identified whether there was prescription drug coverage (yes or no). We also examined income in MCBS, which is underreported and therefore we inflated the self-reported income by 20% as recommended previously and converted the adjusted income to the federal poverty levels.¹⁹ Poverty status was classified based on Medicaid status and federal poverty level (FPL). Patients were stratified into 5 mutually-exclusive categories: Medicaid, 0–100% FPL, 101–150% FPL, 151–200% FPL, and 201+% FPL as others have done.²⁰

Analysis

First we described the annual rates (and 95% confidence intervals [CIs]) of socio-demographic and health characteristics of the study population, 2000 to 2006, weighted to represent the overall rheumatoid arthritis population of community-dwelling Medicare beneficiaries. Then we calculated the annual prevalence of nonbiologic and biologic DMARDs (specifically the proportion of rheumatoid arthritis patients who received at least 1 prescription in each year) and the mean values of functional status, and health care expenditures (and 95% confidence intervals). Subsequently we tested for trends over time were using weighted regressions using ordinary least squares accounting for survey design. All analyses were conducted using SAS version 9.2. The a priori level of statistical significance was $p=0.05$. This study was reviewed and approved by the Institutional Review Board at the University of Massachusetts.

Results

We identified rheumatoid arthritis patients annually between 2000 and 2006, most of whom were women living in metropolitan areas (Table 1). Most patients (70%) were identified based on 2 ICD-9 diagnoses of rheumatoid arthritis within 1 calendar year. Approximately two-thirds of patients reported both a diagnosis of rheumatoid arthritis and had at least one ICD-9 code for rheumatoid arthritis. In 2000, 49% of the sample had at least one ICD-9 diagnosis of rheumatoid arthritis as well as use of a nonbiologic or biologic DMARD. This increased to 59% by 2006. The mean age was 69.1 to 71.7 years. Over time there were greater numbers of Hispanic patients and fewer Whites. The proportion of patients with prescription drug coverage increased from 85.3% in 2000 to 97.1% in 2006 ($p=0.0001$). There were no significant changes in poverty status or comorbidity burden. However, self-reported health status of excellent, very good or good increased from 43.0% in 2000 to 55.6% in 2006.

As shown in Table 2, use of cytotoxic DMARDs remained stable from 2000 to 2006 (28.5% in 2000 vs. 34.1% in 2006, $p=0.19$), as did use of noncytotoxic DMARDs (25.2% in 2000 vs. 23.2% in 2006, $p=0.83$). Between 2000 and 2006, 2.2–5.5% of patients used etanercept ($p=0.32$) and 1.3–4.9% used infliximab ($p=0.54$). Adalimumab, which was approved in 2003 by the FDA, was used in 0.7 to 5.3% of patients ($p=0.001$). Overall use of both the noncytotoxic and cytotoxic DMARDs remained at a stable rate ranging from one-quarter to one-third of patients receiving each drug class.

In contrast, use of biologics increased substantially (Figure 1A). Between 2000 and 2006, the proportion of biologic users increased from 4.6% in 2000 to 13.2% in 2006 ($p=0.006$). In addition, Figure 1 shows the adoption of the biologics and the functional status assessments over the same time period. Concurrent to the increase in the use of biologics from 2000 to 2006, we also observed a significant improvement in functional status measures (Figure 1B). The mean activities of daily living score (range 0 to 6; higher score denotes greater limitations) was 1.35 in 2000 as compared to 1.12 in 2006 ($p=0.034$).

Table 3 summarizes the changes in health care expenditures during the study. Total costs for ambulatory DMARD medications increased by almost 150% (\$396 in 2000 to \$984 in 2006, $p=0.014$), while costs for all prescription medications (not just DMARDs) increased by 77% (\$2645 in 2000 to \$4680 in 2006, $p=0.0001$). However, out of pocket costs remained stable over the time period (\$842 in 2000 to \$832 in 2006, $p=0.68$). Total medical costs increased slightly but the trend was not significant (Table 3). However, there was a significant increase in the mean proportion of total medical costs attributable to prescription medications. In 2000, the mean proportion of medical costs attributable to prescription medications was 30.0% as compared to 37.5% in 2006 ($p=0.001$).

Discussion

Between 2000 and 2006, the use of biologic agents in older adults with rheumatoid arthritis increased from 4.6% in 2000 to 13.2% in 2006. This increase occurred during a period of expansion in prescription drug coverage for these agents. During the same period, we also observed statistically significant improvement in patient-reported functional status however the magnitude of the improvement is of unclear clinical significance. In addition, the proportion of patients rating their health status as excellent, very good or good increased by 30% from 43.0% in 2000 to 55.6% in 2006. While large increases in total prescription medication costs were observed, over the same time period out-of-pocket costs for prescription drug remained constant.

The increased use of biologic utilization without a concomitant rise in out-of-pocket costs suggests that recent policy changes have enabled increased access to medications without increasing drug spending for beneficiaries, which has been seen in other chronic medical conditions since the introduction of Part D.¹⁴ Medical care for rheumatoid arthritis is expensive; individuals with rheumatoid arthritis have higher medical expenditures than persons without arthritis.²¹ Specifically Yelin found that the amount Americans spent on arthritis medications more than doubled between 1998 and 2003.²² For elderly patients, greater medical expenses combined with limited income can result in increased out of pocket burden. Other research has shown that drug benefit generosity influences the likelihood that rheumatoid arthritis patients will initiate and continue a biologic agent.²³ Based on our results, it appears that the Medicare Replacement Drug Demonstration (MRDD) program and Medicare Part D likely controlled out of pocket costs and potentially permitted increased utilization of biologics in these patients. The MRDD program was created by Congress to provide temporary drug insurance until the start of Medicare Part D. Low income vulnerable Medicare beneficiaries with select conditions, including rheumatoid

arthritis, without comprehensive drug insurance coverage were targeted for MRDD enrollment. MRDD was structured to have similar patient cost-sharing arrangements as the anticipated standard Medicare Part D benefit. For rheumatoid arthritis, the program covered self-injectable medications including adalimumab and etanercept.²⁴ This was followed by Medicare Part D in 2006, which has been successful in reducing the out of pocket costs among Medicare beneficiaries.²⁵

While the adoption of biologic use in our population increased substantially, it is still less than what has been observed in younger rheumatoid arthritis patients.^{26,27} For example, in a younger population where over 60% had commercial insurance, biologic use increased 800% over the same time period resulting in 26% of the sample receiving biologic agents in 2006—double the increase among Medicare patients.²⁸ While financial concerns may play a role, treatment decisions may be influenced by the age of the patient. Even though traditional DMARDs and biologics are both safe and efficacious in the elderly^{29–33}, rheumatologists state they are less likely to treat these patients aggressively.¹⁰ This has been borne out in clinical practice with biologics being used less often in older rheumatoid arthritis patients as compared to younger patients taking into account disease activity, disease duration and comorbidities.³⁴ While elderly patients may require more monitoring because of comorbidity, polypharmacy and age related changes in pharmacokinetics and dynamics, the American College of Rheumatology treatment recommendations do not suggest different rheumatoid arthritis treatment strategies based on patient age or disease duration.¹ While pharmacotherapeutic decision-making in the elderly can be complex, the beneficial impact of biologics with regard to functional status and independence should be examined as older patients and providers weigh the risks and benefits of treatment.

Due to the cross-sectional nature of the study, small sample size and the low proportion of people using biologic agents, this work cannot examine whether there is a causal relationship between drug coverage and health outcomes. For example, it is possible that more aggressive treatment approaches led to simultaneous increased use of biologics and improvement in functional status. However, the concurrent improvements in self-reported health status and functional status deserve further study at the population level. Other limitations include no information on rheumatoid arthritis disease activity or disease severity thus we are unable to examine whether all patients who were candidates for biologic drugs received them. We also cannot assess whether patients declined use of biologics or whether they discontinued the agents due to clinical or financial reasons. Medication use was identified based on patient self-report of medications, thus there may be some undercounting. Given the small numbers of biologic users, our estimates of use for each of the specific agents could have been influenced by the sampling strategy. As with all studies using ICD-9 codes to identify patients, misclassification is a concern. However, studies using Medicare claims have reported a sensitivity of 65 to 90% and a high positive predictive value.^{35,36} To try to improve sensitivity, we used three different strategies to identify our population.

In summary, we identified a nationally-representative sample of rheumatoid arthritis patients annually from 2000 through 2006. We were able to measure use of biologic and nonbiologic DMARDs in conjunction with patient-reported functional status and health status as well as associated costs. Over those 7 years, there was a dramatic increase in the number of patients receiving biologic agents. While these agents are more than 10 times more expensive than traditional agents, patient out-of-pocket expenses did not increase suggesting recent health care policy changes have been successful in tempering the direct financial burden of medication costs for Medicare patients with rheumatoid arthritis.

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Dr. Harrold had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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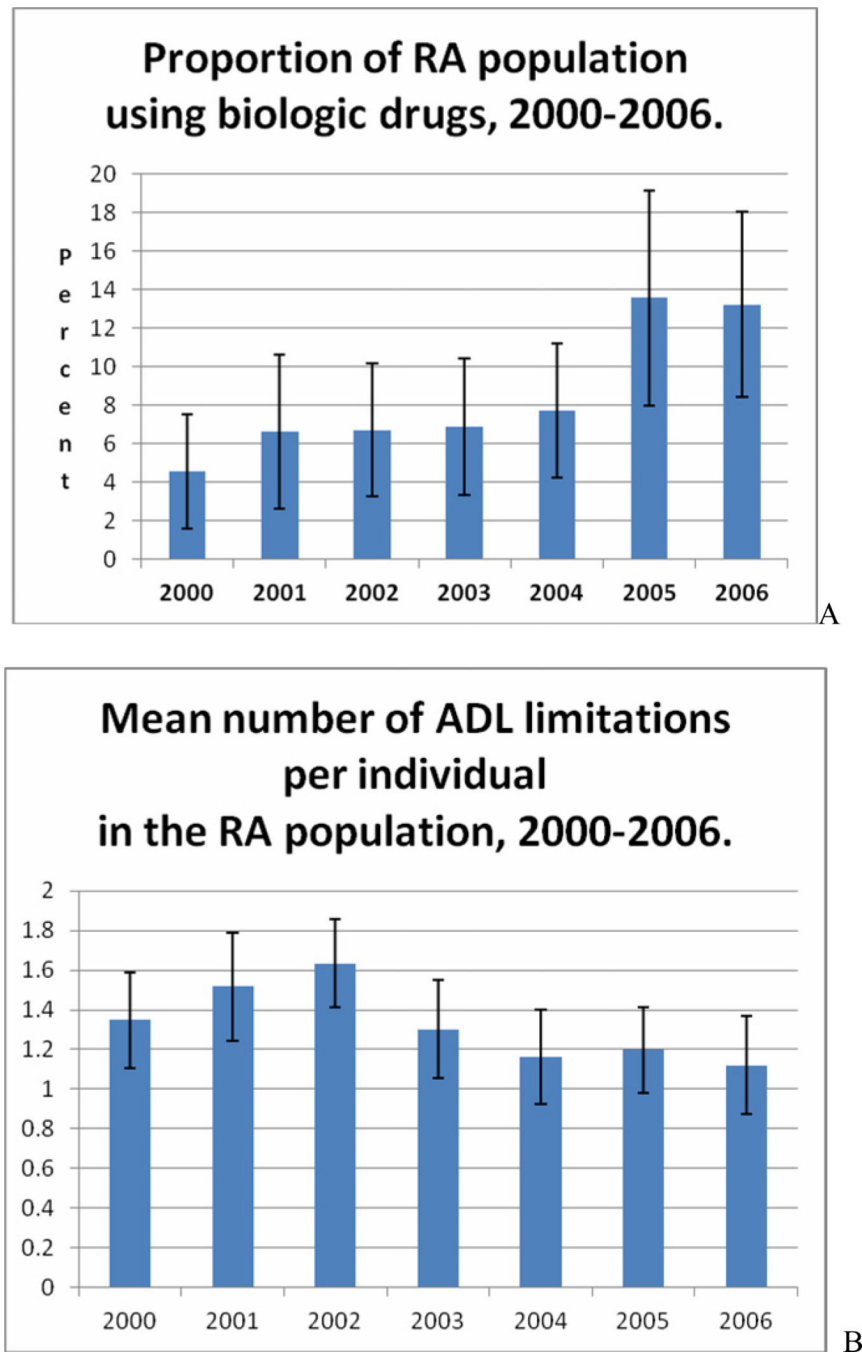


Figure 1. Time trends in the use of biologics and functional status, 2000–2006.*
*RA = Rheumatoid Arthritis; ADL = Activities of Daily Living

Table 1

Trends over time in the characteristics of RA patients enrolled in Medicare (only even years shown).

	2000	2002	2004	2006	P value
unweighted n	225	260	253	247	
age in year, mean (SE)	70.5 (0.81)	71.7 (0.62)	69.9 (0.75)	69.1 (0.76)	0.081
female gender (%)	77.0	75.5	79.6	79.3	0.237
Race/ethnicity (%)					0.016
Hispanic	5.6	7.5	9.3	12.6	
Black/non-Hispanic	12.7	7.5	11.2	12.1	
White	76.4	82.1	74.4	71.9	
Residence (%)					0.138
Rural	26.8	27.1	26.2	20.0	
Metropolitan	73.2	72.9	73.8	80.0	
Prescription drug coverage (%)	85.3	89.7	84.9	97.1	0.001
Poverty status					0.625
Medicaid	14.2	10.7	15.6	12.7	
0–100% FPL	17.4	15.8	19.9	17.4	
101–150% FPL	17.1	13.2	15.7	12.7	
151–200% FPL	17.5	27.5	18.6	25.8	
201+% FPL	33.7	32.8	30.2	31.4	
Comorbidity burden (%)					0.105
0	15.0	8.9	10.0	11.6	
1 to 2	41.3	51.6	47.0	47.3	
3 or more	58.1	39.5	43.0	41.1	
Self-reported health status (%)					0.015
excellent/very good/good	43.0	44.0	48.7	55.6	
fair/poor	57.0	56.0	51.3	44.4	

Table 2

Trends in the use of disease modifying anti-rheumatic drugs (DMARDs) (only even years shown).

Medication	2000	2002	2004	2006	p value
Noncytotoxic dmards (% , SE)	25.2 (3.3)	21.4 (2.9)	22.0 (2.8)	23.2 (2.7)	0.829
Cytotoxic dmards** (% , SE)	28.5 (3.3)	26.9 (3.0)	32.6 (3.8)	34.1 (3.6)	0.193
Biologic agent***					
Adalimumab (% , SE)	0.0	0.0	0.7 (0.4)	5.3 (1.6)	0.001
Etanercept (% , SE)	3.3 (1.3)	2.2 (1.0)	4.6 (1.3)	3.5 (1.2)	0.320
Infliximab (% , SE)	1.3 (0.7)	4.9 (1.5)	2.5 (1.0)	4.4 (1.4)	0.544

* noncytotoxic: hydroxychloroquine and sulfasalazine

** cytotoxic: methotrexate and leflunomide

*** biologic use included the anti-TNFs only

Trends in ambulatory prescription costs, out of pocket costs, total medical costs and the proportion of costs due to prescription drugs (2006 dollars) (only even years shown).

Table 3

Medical Care	2000	2002	2004	2006	P value
Ambulatory prescription costs, mean (\$, SE)	2645 (172)	3270 (184)	3726 (243)	4680 (315)	0.0001
RA specific ambulatory prescription costs, mean (\$, SE)	396 (62)	592 (98)	547 (78)	984 (166)	0.014
Out-of-pocket prescription costs, mean (\$, SE)	842 (82)	854 (55)	924 (65)1	832 (68)	0.682
Total medical costs, mean (\$, SE)	16563 (1714)	18310 (1484)	17783 (1714)	19510 (1365)	0.070
Proportion of total medical costs due to prescription medications (% , SE)	30.2 (1.90)	31.9 (1.77)	36.6 (1.97)	37.5 (1.93)	0.001