Research Square

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Physical Restraint of Dementia Patients in Acute-Care Hospitals During the COVID-19 Pandemic: A Cohort Analysis in Japan

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Abstract

Background*:* The coronavirus disease (COVID-19) pandemic has caused unprecedented challenges for medical staff worldwide, especially for those working in hospitals in which COVID-19-positive or -suspected patients are being treated. The announcement of COVID-19 hospital restrictions by the Japanese government has led to several limitations in hospital care, including an increased use of physical restraints, that could affect the care of elderly dementia patients. However, few studies have empirically validated the impact of physical restraint use during the COVID-19 pandemic. We aimed to evaluate the impact of regulatory changes, consequent to the pandemic, on physical restraint use among elderly dementia patients in acute care hospitals.

Methods: In this retrospective cohort study, we extracted the data of elderly patients (age >65 years) who received dementia care in acute care hospitals to which COVID-19-positive or -suspected patients were admitted between July 1, 2018 and June 30, 2020. We calculated descriptive statistics to compare the year-on-year trend in 2-week intervals and conducted an interrupted time-series analysis to validate the changes in the use of physical restraint.

Results: The year-on-year trend in the number of patients who were physically restrained per 1,000 hospital admissions increased after the government's announcement of COVID-19 restrictions, with a maximum incidence of 111.4% between the 47th and 48th week after the announcement. Additionally, a significant increase in the use of physical restraints in elderly dementia patients was noted (p=.002).

Conclusions: Elderly dementia patients who required personal care experienced an obvious and significant increase in the use of physical restraints during the COVID-19 pandemic. Understanding the causes and mechanisms underlying an increased use of physical restraints in dementia patients can help design more effective care protocols for similar future situations.

Background

The rapid spread of coronavirus disease (COVID-19), which first appeared in Wuhan, China, has progressively increased and continues to disrupt healthcare systems worldwide.[1] In acute care hospitals, especially those treating COVID-19 patients, the medical staff face difficulties in providing routine care owing to patient triage, social distancing, and shortage of resources, such as finances, medical supplies, and manpower.[2–4] To manage the pandemic, the Japanese government announced hospital restrictions, including those pertaining to family visits, at the end of February 2020. These changes in hospital care systems could exacerbate progressive cognitive disfunction and worsen behavioral and psychological symptoms in dementia patients and consequently result in a higher distress to both patients and medical staff.[5]

The use of physical restraint for dementia patients has been discussed in recent years. Physical restraint is often used in acute care settings[6–8] and includes 11 means of mechanical restraint based on national

guidelines for the prevention of physical restraints.[9] However, such means may confer critical medical disadvantages for patients, including restraint device-related injuries, such as asphyxiation or chest compression, and immobility-related complications, such as deep vein thrombosis, pulmonary embolism, aspiration pneumonia, and rhabdomyolysis. [10–13]

Owing to the abovementioned disadvantages and ethical concerns, recommendations to avoid the use of physical restraint have been made worldwide, including in Japan.[14–16] Since 2016, in Japan, the Ministry of Health, Labour and Welfare (MHLW) has factored in an additional fee in the universal benefit scheme for dementia care of patients without severe disorientation who need personal care, wherein a financial disincentive of 40% reduction is provided if physical restraint is used.[9,17] As dementia symptoms may not be recognizable in routine care, this benefit can be particularly applicable to patients who have communication-related challenges or symptoms that inhibit their daily life without diagnosis of dementia.[18] To be eligible to obtain the stipulated benefit, nurses need to be trained for dementia care, and a standardized protocol for mechanical and chemical restraint procedures for sedation is required.[17]

Providing routine comprehensive care for dementia patients may be challenging during the COVID-19 pandemic.[5] However, only few studies have explored the impact of the COVID-19 pandemic on dementia care, especially with regard to physical restraint use in dementia patients. Therefore, in this retrospective cohort study, we aimed to evaluate the impact of regulatory changes consequent to the COVID-19 pandemic on the use of physical restraints among dementia patients in acute care hospitals. We hypothesized that dementia patients are more likely to be physical restrained during the pandemic in acute care hospitals that treat COVID-19 patients than during pandemic-free time periods.

Methods

Data Source

We used the Diagnosis Procedure Combination (DPC) data from the Quality Indicator/Improvement Project (QIP) database in Japan. The QIP participant hospitals provide claim data and DPC data to improve their system and quality of care using quality indicators. Across Japan, more than 200 QIP participant hospitals, both public and private, of various sizes were included; in these hospitals, the number of general beds (hospital beds not earmarked as psychiatric, infectious diseases, and tuberculosis beds) according to the Japanese classification of hospital beds ranged from 30 to 1,151 in 2019.

The DPC/per-diem payment system (PDPS) is a Japanese prospective payment system that is used in acute care hospitals and is comparable to diagnosis-related databases in the United States.[19,20] A total of 1,730 hospitals adopted the DPC/PDPS in 2018, which accounted for 54% of all general beds in Japanese hospitals.[21,22] However, the DPC data do not include detailed information on the level of nursing care; instead, they provide information such as primary diagnoses, comorbidities (identified using

the International Classification of Diseases, 10th Revision [ICD-10] codes), drug or device prescriptions, and codes corresponding to the performed medical procedures as stated in the discharge summary.

Study Population

The eligibility criteria for inclusion in this study were as follows: age > 65 years; availability of admission and discharge summary for 104 weeks between July 1, 2018 and June 27, 2020; and application of dementia care benefit during admission. We excluded patients who were admitted to the intensive care unit or were hospitalized for COVID-19 treatment because their clinical characteristics and disease severity greatly differed from those of other dementia patients, and therefore, the use of physical restraints in the former could be a consequence of other factors/mechanisms.

Variables

We obtained information on patients' sex, age, body mass index (BMI), ambulance use, admission type, admission pathway, comorbidity indices (Charlson Comorbidity Index [CCI]),[23] whether a surgical procedure was conducted, reason for admission based on the ICD-10 codes (infection, neoplasm, endocrine, mental and behavioral, nervous, circulatory, respiratory, digestive, musculoskeletal, genitourinary, injury, and others), and length of stay (LOS) to examine the baseline patient characteristics. The patients were assigned to three groups based on age (65–74, 75–84, and ≥85 years) and BMI (< 18.5, 18.5–24.9, and ≥25.0 kg/m^2). LOS is presented as the median and interquartile range. The outcome of interest was the frequency of physical restraint use among patients who applied for dementia care benefit.

Statistical Analysis

First, we divided the 104-week period into 52 categories of 2-week intervals based on the admission data and specified the appropriate timing category of the announcement (44th out of 52 categories) as the point of implementation. We divided our datasets into two periods for the interrupted time-series (ITS) analysis: pre- (1–43) and post-announcement (44–52). Comparisons were conducted using the chi-square or Fisher's exact test or the Kruskal–Wallis rank sum test, as appropriate. Data on BMI were missing in 9.6% of the sample (categorized as unknown). Sensitivity analysis using complete case analysis indicated that the missing data did not affect the results of the study. Thereafter, to examine the year-over-year trend, the number of patients who were physically restrained per 1,000 hospitalizations as indicated for every 2 weeks between July 1, 2019 and June 27, 2020 were compared with that between July 1, 2018 and June 27, 2019. Finally, we used ITS, including segmented regressions, to ascertain the impact of the governmental announcement of COVID-19 restrictions on the use of physical restraint for patients. We statistically assessed the changes in the number of patients who were physically restrained per 1,000 hospitalizations and who were provided with the dementia care benefit based on the date of admission adjusted for seasonality through a Fourier term.[24] The level of statistical significance was set at $p < .05$ (two-tailed). Statistical analyses were performed with R version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

The study protocol was approved by the Ethics Committee. This study was conducted in accordance with the ethical guidelines issued by the Japanese National Government for medical and health research involving human participants. The data were anonymized, and the requirement for informed consent was waived by the approving authority.

Results

We identified 111,799 patients from 115 hospitals to which COVID-19-positive patients were admitted; 41.3% of patients were male. After excluding patients admitted in the ICU (n = 3,075) and those being treated for COVID-19 (n = 182), 108,542 patients were finally recognized as the study sample (Fig. 1). Table 1 shows the demographics of patients who were eligible for study inclusion from before to after the announcement of COVID-19 restrictions by the MHLW. All variables are expressed as absolute numbers (n) and relative frequencies (%). Among the patients, those aged > 85 years comprised more than half of the study population, and most patients needed urgent or emergent hospitalization (87.9% vs. 88.4%). The percentages of ambulance use (51.7% vs. 52.3%; $p = .19$) and subjection to surgical procedure (29.6% vs. 30.1%; $p = .30$) were marginally high, whereas the percentage of CCI > 2 was low (21.4% vs. 19.8%; $p < .001$) after the intervention. Figure 2 displays the number of patients who were physically restrained per 1,000 hospitalizations (shown by the bars) and the year-on-year trend (shown on the line) based on the date of admission. After the 36th week of announcement by the MHLW, the year-on-year trend of cases that required physical restriction per 1,000 hospitalizations increased, with a maximum of 111.4% during the 47th and 48th week. According to the ITS analysis, the number of patients who were physically restrained per 1,000 hospitalizations statistically increased after the MHLW's announcement of COVID-19 restrictions (Fig. 3; $p < .002$).

Table 1
Characteristics of patients who received dementia care before and after COVID-19-related regulatory changes

Characteristics	Pre-intervention	Post-intervention	*p*
Number of patients	93,478	15,064	
Male, n (%)	39,908 (42.7)	6,295 (41.8)	.038
Age, years, mean (SD)	84.92 (7.40)	85.18 (7.36)	< .001
Age category, years, n (%)			.013
65–74	8,973 (9.6)	1,346 (8.9)	
75–84	32,356 (34.6)	5,165 (34.3)	
≥85	52,149 (55.8)	8,553 (56.8)	
Body mass index category, kg/m^2, n (%)			< .001
<18.5	27,554 (29.5)	4,226 (28.1)	
18.5–24.9	47,331 (50.6)	7,763 (51.5)	
≥25.0	9,521 (10.2)	1,625 (10.8)	
Unknown	9,072 (9.7)	1,450 (9.6)	
Ambulance use, n (%)	48,308 (51.7)	7,872 (52.3)	.19
Urgent or emergent admission, n (%)	82,196 (87.9)	13,319 (88.4)	.10
Admission pathway, n (%)			.08
Home	59,889 (64.1)	9,516 (63.2)	
Hospital or nursing home	33,538 (35.9)	5,542 (36.8)	
Other	51 (0.1)	6 (0.0)	
Charlson Comorbidity Index > 2, n (%)	19,970 (21.4)	2,985 (19.8)	< .001
Surgery during admission, n (%)	27,702 (29.6)	4,527 (30.1)	.30
Reason for admission, n (%)			< .001
Infection, n (%)	2,534 (2.7)	458 (3.0)	
Neoplasm, n (%)	6,130 (6.6)	1,011 (6.7)	
Endocrine, n (%)	4,528 (4.8)	720 (4.8)	
Mental and behavioral, n (%)	358 (0.4)	48 (0.3)	
Nervous, n (%)	2,948 (3.2)	436 (2.9)	

Characteristics	Pre-intervention	Post-intervention	*p*
Circulatory, n (%)	17,578 (18.8)	2,620 (17.4)	
Respiratory, n (%)	19,686 (21.1)	2,759 (18.3)	
Digestive, n (%)	10,043 (10.7)	1,830 (12.1)	
Musculoskeletal, n (%)	2,421 (2.6)	351 (2.3)	
Genitourinary, n (%)	7,735 (8.3)	1,427 (9.5)	
Injury, n (%)	12,805 (13.7)	2,188 (14.5)	
Others, n (%)	6,712 (7.2)	1,216 (8.1)	
Length of stay, median (IQR)	21 (12, 37)	17 (12, 38)	< .001

Discussion

This study showed the trends of dementia patients requiring nursing care who were physically restrained per 1,000 hospitalizations and tracked important changes in this regard during the COVID-19 pandemic in Japan. The main finding of our study was that following the MHLW's announcement of COVID-19 hospital restrictions, dementia patients who required nursing care were significantly more likely to be physical restrained.

Dementia has increasingly gained importance as a public health concern because of the increase in aging societies worldwide.[25] The increasing prevalence of dementia in older adults has resulted in a situation where medical staff in acute care hospitals often need to provide dementia care to elderly patients, although the patients are admitted for acute diseases.[26] Moreover, hospital staff is often not sufficiently trained to provide care for dementia patients. Physical restraining is often performed in acute care settings, especially in elderly patients and those with dementia,[7,8,15,27–29] to prevent falls and self-extubation and because of low availability of medical staff and inadequate resources to constantly monitor at-risk patients owing to the large workload of the hospital staff.[6,30] However, physical restraints should be avoided, wherever possible, in conformance with recommendations that have been issued worldwide, including in Japan.[14–17]

We considered the following two major reasons for the increased use of physical restraints in elderly dementia patients compared with recent trends in the previous year: 1) patient factors and 2) factors associated with the care system.

The former is attributable to the hospitalization of elderly patients with increased progression of cognitive impairment because of the COVID-19 pandemic.[31] During the COVID-19 pandemic, many people refrained from social gatherings and other interpersonal communications even with their families. The Japanese government repeatedly made announcements asking citizens to reduce physical contact with others by

80% using the phrase “Three Cs”: avoiding closed spaces, crowded places, and close-contact settings.[32] However, social isolation is considered to be associated with poor cognitive functioning in older adults.[33] The Japan Association of Geriatric Health Services Facilities and Hiroshima University published findings that restrictions on going out and meeting visitors, including family and friends, worsened the cognitive and physical functions of dementia patients.[31] Moreover, social restrictions have had a substantial impact on the management of outpatient clinics because of cancelations or triage of patients.[34] Dementia patients with more severe cognitive function impairment could possibly have been hospitalized during the COVID-19 pandemic, which led to the increased frequency of physical restraint.

Factors associated with the care system and quality of care in general hospitals could have changed during the COVID-19 pandemic. Dementia patients often experience a challenging environment during hospitalization for acute diseases, and therefore, communicating with visitors, especially family members, is important to maintain their cognitive function.[29,35,36] The Centers for Disease Control and Prevention guidance allows care partners to visit patients if they are essential to the patients’ physical or emotional well-being, even during the COVID-19 pandemic.[37] Furthermore, use of telemedicine and digital technology can be helpful for the management of chronic neurological disease, including dementia and cognitive impairment.[38] In addition, the mental and physical statuses of medical staff are important to provide the best care for patients. During the COVID-19 outbreak, the medical staff were under pressure owing to the heavier workload, risk of infection, and defamation in public spaces.[39–41] Nurses are required to take care of several patients at once during pandemics, such as the COVID-19 pandemic,[42] while wearing personal protective equipment, which makes communication more complex. The threshold for physically restraining elderly dementia patients may have been lowered owing to changes in the care system that have occurred consequent to the implementation of hospital strategies or due to increased strain on medical staff.

This study had several limitations. First, the severity of manpower shortage and the extent to which the restriction regarding family visitation was strictly enforced were unclear in the target hospitals. This study included hospitals to which COVID-19-positive or -suspected patients were admitted; more thorough infection control measures were considered to be practiced in these hospitals than in hospitals that did not accept COVID-19-positive or -suspected patients. However, we could not consider and evaluate different burdens on medical staff owing to differences in the number of admissions of COVID-19-positive patients in the target hospitals. To manage restriction on in-person visits owing to the COVID-19 pandemic, some hospitals have been attempting to ensure a virtual connection between patients and their loved ones via tablets or smartphones. Despite the limitations in the use of technology, including difficulty in hearing over devices, patients can reap benefits by communicating with their family members.[43] Second, we could not detect the type or severity of dementia, which is often not recognized in general hospitals,[18] because the applicable benefit did not require precise information about dementia. However, patients who were eligible for inclusion in this study were patients who were judged by medical staff, trained in dementia care, as having dementia or an equivalent cognitive impairment that interfered with their daily lives and necessitated nursing care. [17] Moreover, the dementia care benefit cannot be

applied to those who have severe disorientation (indicated by a Glasgow Coma Scale score < 9).[9,17] Therefore, we believe that patients with dementia of severity within a certain range were selected.

A strength of our study is its large sample size. Multicomponent interventions that increase medical staff awareness have limited effectiveness in reducing physical restraint use[16]; however, we believe that examining the current situation during the pandemic can significantly help prepare for similar future circumstances.

Conclusions

We demonstrated and validated a trend of increased use of physical restraints for elderly dementia patients using ITS analyses of administrative data. Elderly dementia patients who require personal care might be more likely to be physical restrained during the COVID-19 pandemic. While limited social interaction is inevitable to prevent the spread of the COVID-19 infection, the promotion of telemedicine and mental or physical care for medical staff may be important in reducing the use of physical restraints among dementia care patients. Future research should identify causative factors, including patient environment and stress among medical staff, that lead to the increased use of physical restraints and explore avenues to reduce this use in future pandemics.

List Of Abbreviations

COVID-19, coronavirus disease; MHLW, Ministry of Health, Labour and Welfare; PDPS, per-diem payment system; DPC, Diagnosis Procedure Combination; QIP, Quality Indicator/Improvement Project; CCI, Charlson Comorbidity Index; ICD-10, International Classification of Diseases, 10th Revision; LOS, length of stay; ITS, interrupted time-series

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of Kyoto University Graduate School, Kyoto, Japan (R0135). This study was conducted in accordance with the ethical guidelines issued by the Japanese National Government for medical and health research involving human participants. The data were anonymized, and the requirement for informed consent was waived by the approving authority. The study complied with the personal information protection policy for research and the protection of trial subjects stated in the Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

TO, JS, and YI developed the study concept and design; TO, JS, SK, and YI acquired the study data; TO, DT, TM, and YI analyzed and interpreted the data; TO and YI drafted the manuscript; and TO and YI critically revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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Figures

Figure 1

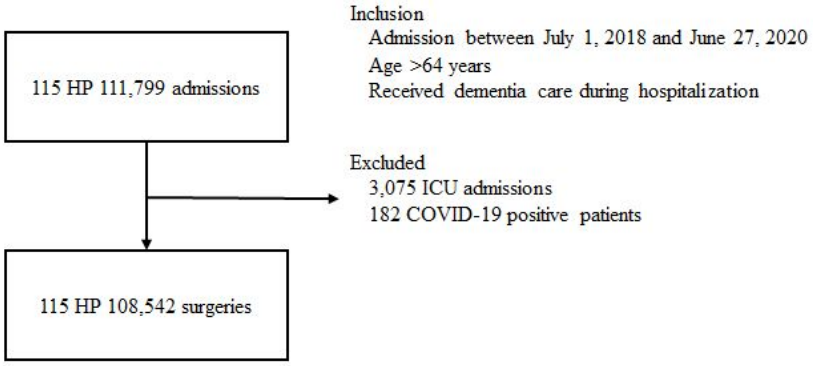

Figure 1

Flowchart depicting patient progression through this study based on the eligibility and exclusion criteria
HP, hospitals

Figure 2

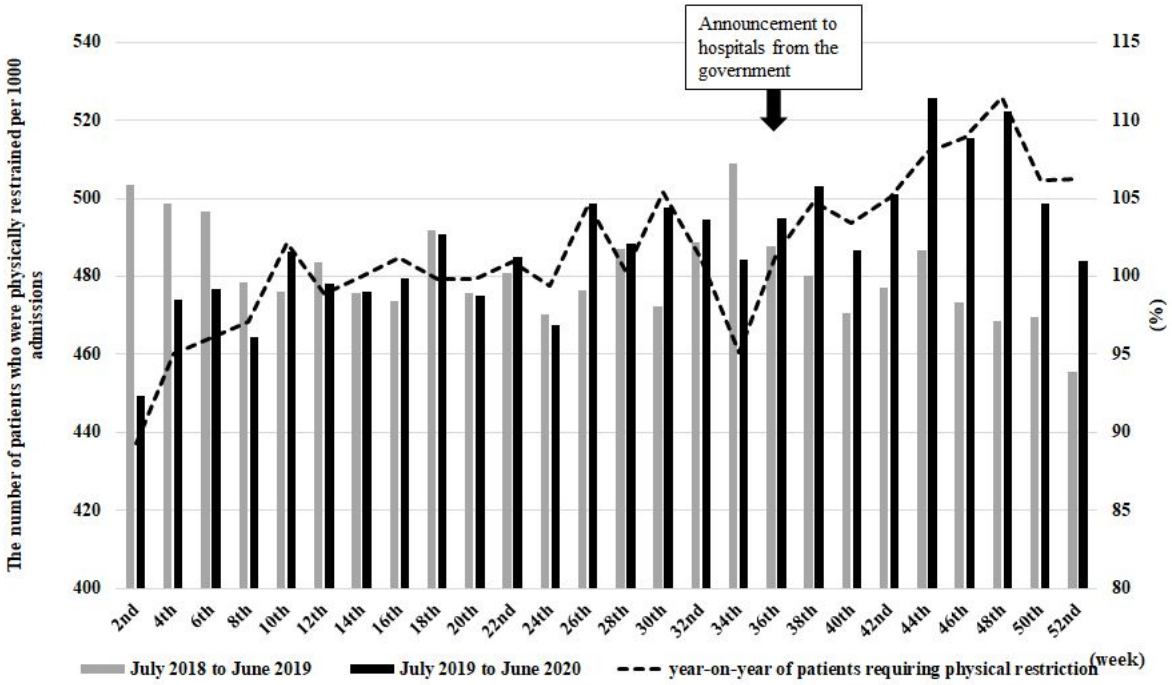

Figure 2

Comparison of the number of patients restrained and the year-on-year trend The number of patients who were physically restrained per 1,000 hospital admissions for 2-week intervals between July 1, 2019 and June 27, 2020 was compared to the number of patients restrained between July 1, 2018 and June 27, 2019 (shown in the bar graph), with a year-on-year trend (shown in the line graph).

Figure 3

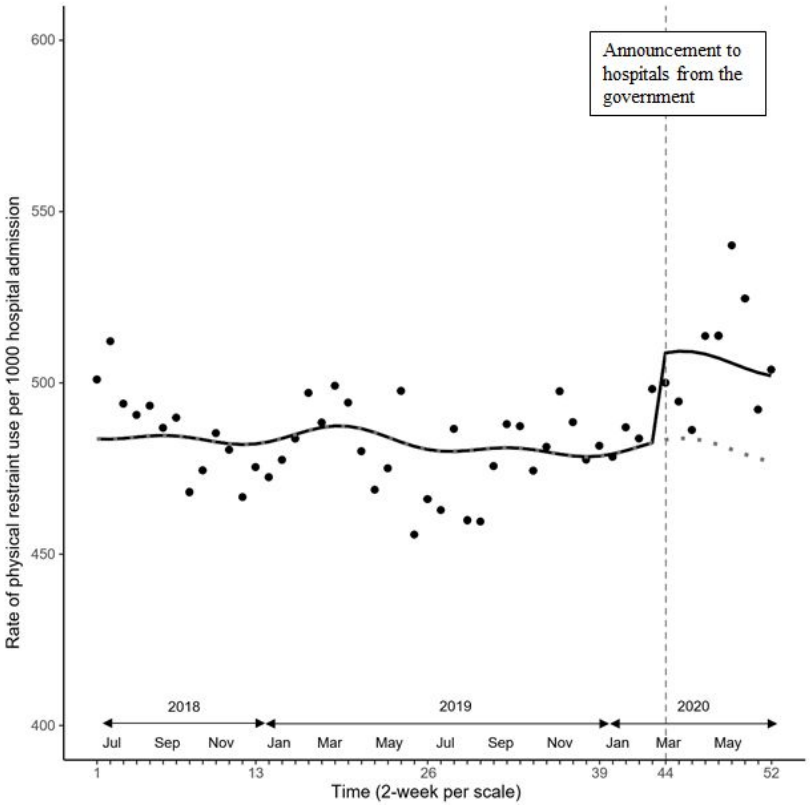

Figure 3

Interrupted time-series analysis of the number of patients who were restrained The number of patients who were physically restrained per 1,000 hospital admissions over time was evaluated with an interrupted time-series analysis including segmented regressions (p=.001).