

DPC データを用いた総合診療系医と領域別専門医の必要数算定の要素解析の研究

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研究要旨

総合診療系医と領域別専門医の必要数算定を推進するには、糖尿病の疾病機序にそって、罹患率および介入行為数と、診療介入に伴う医師の人的医療資源の消費量（人数と時間など）を対応付けしたデータの解析が必要となる。しかし我が国には、この検討に耐えうるデータが存在しないため、DPC 調査のデータベースを用いて推計要素の解析を試みた。その結果、糖尿病（主病名および併発病名）に罹患した症例で、手術適用となった入院受療の件数、平均年齢、在院日数などについて把握が可能であった。以上より、必要医師人数の算定要素の基礎資料として、DPC データが有用であることを明らかにした。また、結果の解釈や補正の実施に必要な、要素間の関係について分析を行ったところ、インスリン依存性糖尿病（IDDM）に罹患した手術適用症例は、年齢と在院日数の相関関係が他の疾病分類よりも統計的に強く示唆された。

A. 研究目的

当該研究全体では、医療需要に対する医療資源の適切配置を論じるために、医療連携モデルを基盤とした総合診療系医と領域別専門医の必要数算定を目的とした。本年度は、方法論の検証も兼ねて糖尿病診療分野を対象に実施された。

当該研究全体では、疾病群別の患者数（診療需要）の調査結果、および診療需要に伴う患者 1 人あたりの診療介入数、医師の必要量（人的医療資源：診療行為別の診療時間、人年単位）の推計結果を、作成した需要供給のモデル（医師の機能分担を含む医療連携モデルも組込）に編入し、総合診療医（かかりつけ医）と各領域の専門医の必要数を求めることを指向している。

この当該研究全体を円滑に推進していくためには、糖尿病の疾病機序（重症化など）にそって、患者数（罹患率）および診療内容（介入行為）と、診療介入に伴う医師の

人的医療資源の消費量（人数と時間）を対応付けしたデータの解析が必要となる。

この患者数および診療内容については、厚生労働省が提供する指定統計などの疫学データの活用を基本とするが、昏睡などの糖尿病急性増悪症例や糖尿病性網膜症の手術症例などの糖尿病が重症化した群、および他目的で入院治療が行われる疾患群における併存症例としての糖尿病の診療介入について、我が国に関する代表性のある情報は殆どないのが現状であった。

そこで、急性期入院診療を主たる目的とする DPC 調査のデータベースから、係わる部分を抽出し必要に応じて他の指定統計などで補正を行いつつ、当該研究全体の分析を推進することにした。

B. 研究方法

前節にて概説した目的にそって、次に示す DPC 関連の情報の収集が可能かどうか、

検討を進め、関わるデータの収集と分析を試みた。

(1) 分析情報の構成

具体的には糖尿病症例（主副病名 E10-12 および周辺疾患）について、以下の4つの情報収集を検討した（図1）。

①糖尿病が重症化した群の件数（症例割合）

・糖尿病急性昏睡症例など主に糖尿病に起因する入院症例または手術症例等に占める比率

②糖尿病を併存症とする群の件数（症例割合）

・入院治療の併存症例としての糖尿病の診療介入群（インスリン治療など）が占める比率

③上記(1)(2)の診療行為の内訳（発生頻度）

・併せて、急性期入院診療における糖尿病関連の診療介入の内訳（紹介など含む）の構成

④その他

その他、入院日数（LOS）や請求点数、年齢構成などの各種の背景情報

(2) 収集する DPC データの範囲

図2に示す概念にそって、次に示すデータの収集を検討した。

①様式1のデータ（糖尿病関連に限定）

②E/F ファイルのデータ（糖尿病関連に限定）

③診療報酬請求の件数と金額（サンプル全体のみ：補正用）

④年齢構成などのデータ（サンプル全体のみ：補正用）

⑤入退院件数などのデータ（サンプル全体のみ：補正用）

（注）その他、患者カバー率や診断分類カバー率、および施設の基本情報（病床数、

専門医の配置などの基準）についても、必要に応じて検討を行う（各種補正に活用する場合）。

(3) 収集する DPC データの対象

(1)で想定する DPC データ群から主副病名 E10-12 などについて、診療行為（請求情報）および管理情報の収集整理を検討した（表1および表2）。なお、それ以外についても図3に示す本研究関連の情報（項目）の収集が可能かどうか検討を進めた。

C. 研究結果

(1) 収集データの範囲

①入院件数

約51万6千件（今回の対象 DPC 全体約255万3千件の20%程度）

②施設件数

854施設（今回の DPC データベースのほぼ全体を網羅）

③情報項目

- ・疾病コード
- ・手術コード
- ・DPCコード
- ・地域コード
- ・在院日数
- ・年齢帯など

③抽出限界

・一部の疾患・行為は、各種の物理的な制約のために抽出することが不可能であった（特に診療行為については、診療報酬点数表の標準コードに拠っているため、多数の制約があった）。

・個票に近い形での抽出情報や医療機関の特定が可能な情報、および請求月情報などについては、外部提供が禁止されているため、収集が不可能であった。

(2) 外科適用症例の基本分析

①入院受療件数の分布

糖尿病（主病名および併発病名）に罹患した症例で、手術適用となった入院受療件数について解析を実施したところ、178,849件（糖尿病罹患者の34.6%、行為と疾病のカウントの関係で症例間に重複あり）の症例が該当した（表3）。

②平均年齢の分布

他の統計データと融合して罹患率や診療件数の推計を行う場合、人口動態などの基礎となる平均年齢の状況は、基本的な要素に位置づけられるが、その分布の状況を整理したところ、69.1歳となっていた（表4）。

③平均在院日数の分布

各種の医療資源の稼働率に汎用的に影響を及ぼす平均在院日数の分布について整理を行ったところ、手術適用となった糖尿病の症例全体の平均で27.6日となっていた（表5）。

(3) 年齢と在院日数の相関分析

糖尿病領域の需要推計や医療資源推計を進めるにあたり、推計に用いる各種要素間の関係を観測し把握することは、他の統計データの母集団との比較、および各種の補正や結果の解釈を行うにあたり、重要と推察される。

そこで、(2)の糖尿病（主病名および併発病名）に罹患した症例で、手術適用となった入院受療群について、年齢と在院日数でスピアマン順位相関分析を実施した。なお論点は、糖尿病という症候群において、病態機序によって年齢と在院日数の関係に差異があるのかどうか、とした。

まず、対象群全体の相関関係を整理したところ、相関係数(rs)が0.0978 ($P<0.001$)

という結果となり、医療分野全体における過去の多くの報告と同様に、年齢と在院日数に相関があることが理解できた（表6）。

続いて、病態機序の異なるインスリン依存性糖尿病（1型糖尿病、IDDM）とインスリン非依存性糖尿病（2型糖尿病、NIDDM）の間で、年齢と在院日数の相関関係に差異があるかどうか、スピアマン順位相関分析で検証した。

解析の結果、インスリン依存性糖尿病（IDDM）における相関係数(rs)が0.2233 ($P<0.001$)、インスリン非依存性糖尿病（NIDDM）での相関係数(rs)が0.0645 ($P<0.005$)という結果となった（表6）。以上から、インスリン依存性糖尿病（IDDM）に罹患した手術適用症例は、年齢と在院日数の相関関係が他の疾病分類よりも統計学的に強いことが示唆された。

D. 考察

医師の必要数算定に関わる需要等の議論を行うにあたり、DPCデータを活用することで、基本的な分析要素の把握が可能と考えられる。しかし、臨床現場で提供される診療行為を細部にわたり医療資源消費の実態と対応付けをすることは、現行の情報分類では不可能と推察される。

これらの限界については、他の統計資料や観測データを融合した多変量なモデルを構築することで、一部については検討を進めることも可能と推察され、今後、研究の発展が望まれるところである。また、ナショナルデータベースであるDPCデータのあり方として、その目的等を鑑みつつ、疫学的な研究テーマなどに対してより積極的に活用していく議論も必要と推察される。

医療資源消費の算定を行うモデルへ導入する可能性のある要素間の関係が、糖尿病型によって統計学的に強弱があるのは、次のような理由が推計される。一つは、母集団のサンプル構造や2次スクリーニングとなる診療行為（本研究では外科療法）の特性に依るものが挙げられる。その他、1型糖尿病の発病は、小児や若年層に多く発病し、急激で重症になり易い特徴があるなど、疾病特性が想像される。

E. 結論

本研究では、医療連携モデルを基盤とした総合診療系医と領域別専門医の必要数算定に資する基本データ収集を目的に、DPCデータの解析を行った。

その結果、糖尿病（主病名および併発病名）に罹患した症例で、手術適用となった入院受療の件数、平均年齢、在院日数などについて把握が可能となり、必要医師人数の算定要素の基礎資料として、DPCデータが有用であることを明らかにした。

また、結果の解釈や補正の実施に必要な、要素間の関係について分析を行ったところ、インスリン依存性糖尿病（1型糖尿病、IDDM）に罹患した手術適用症例は、他の疾病分類より、年齢と在院日数の相関関係が統計学的に強いことが示唆された。

F. 知的財産権の出願・登録状況

| | |
|--------|----|
| 特許取得 | なし |
| 実用新案登録 | なし |
| その他 | なし |

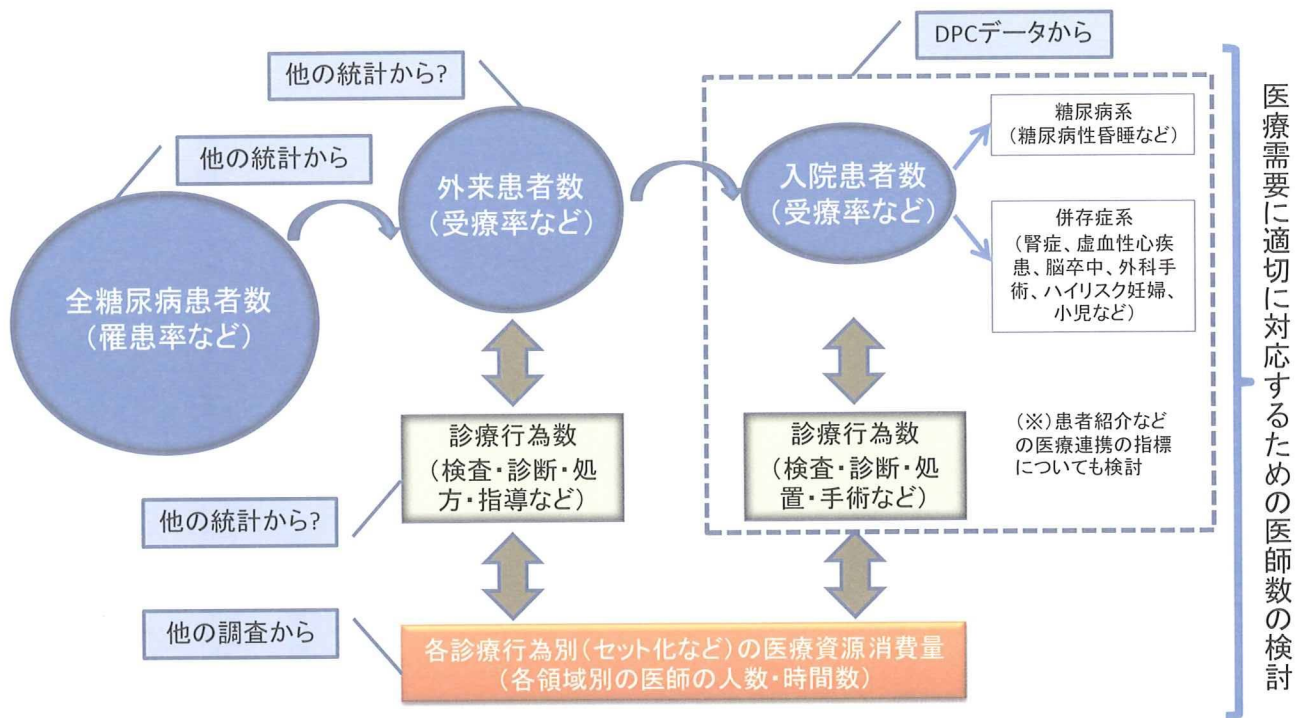


図1 DPC 情報を利用する位置づけ (初期仮説的)

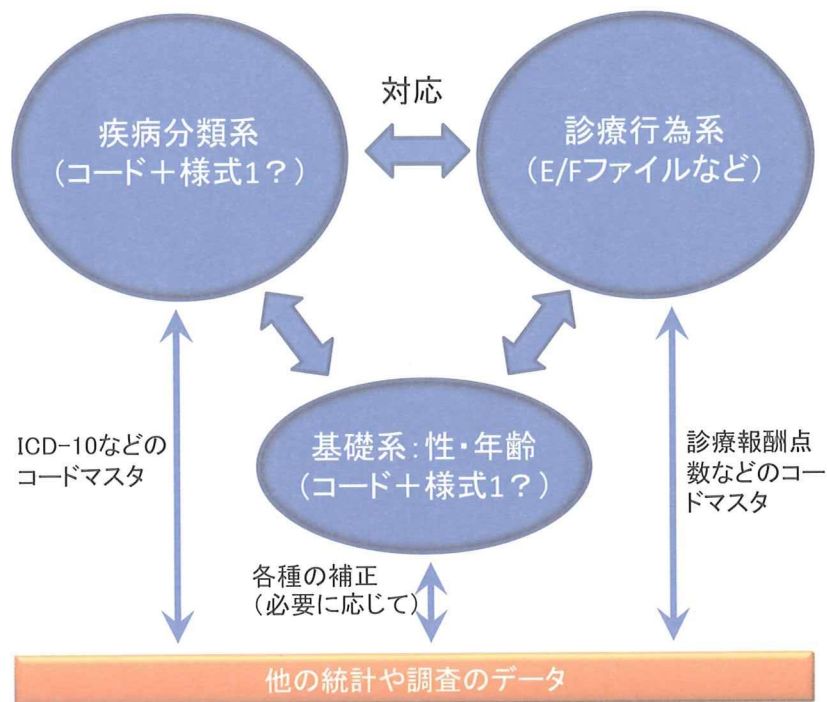


図2 収集を検討する DPC 情報の構造化例

| 疾病群（主病名・副病名） | 診療行為（請求名称） | その他 |
|--|------------------|-------------|
| (E10-12 以外の分類例を特記) | (比較的特殊な診療行為例を特記) | |
| G59 他に分類される疾患における単一ニューロパチ<シ>ニ G59.0 糖尿病性単一ニューロパチ<シ>ニ など | ○医学管理 | ○管理番号 |
| G63 他に分類される疾患における多発(性)ニューロパチ<シ>ニ G63.2 糖尿病性多発(性)ニューロパチ<シ>ニ など | ・糖尿病合併症管理料など | ○施設番号 |
| H36 他に分類される疾患における網膜の障害 H36.0 糖尿病(性)網膜症 など | ○在宅医療 | ○請求年月日 |
| M14 他に分類されるその他の疾患における関節障害 M14.2 糖尿病性関節障害 など | ・血糖自己測定器加算など | ○請求回数 |
| N08 他に分類される疾患における糸球体障害 N08.3 糖尿病における糸球体障害 など | ○検査 | ○請求点数 |
| O24 妊娠中の糖尿病 O24.0 既存のインスリン依存性糖尿病 O24.1 既存のインスリン非依存性糖尿病 O24.2 既存の栄養失調(症)に関連する糖尿病 O24.3 既存の糖尿病、詳細不明 O24.4 妊娠中に発生した糖尿病 O24.9 妊娠中の糖尿病、詳細不明 など | ・人工臓臓など | ○その他基本情報 |
| P70 胎児及び新生児に特異的な一過性糖質代謝障害 P70.0 妊娠性糖尿病母体の児症候群 P70.1 糖尿病母体の児症候群 P70.2 新生児糖尿病 など | ○投薬、注射 | ○ |
| T38 ホルモン類、その合成代替薬及び拮抗薬による中毒、他に分類されないもの T38.3 ホルモン類、その合成代替薬及び拮抗薬による中毒、他に分類されないもの、インスリン及び経口血糖降下薬[抗糖尿病薬] | ○処置 | ○ |
| Y42 治療上の使用により有害作用を引き起こした薬物、薬剤及び生物学的製剤、ホルモン類及びその合成代替薬及び拮抗薬、他に分類されないもの Y42.3 治療上の使用により有害作用を引き起こした薬物、薬剤及び生物学的製剤、ホルモン類及びその合成代替薬及び拮抗薬、他に分類されないもの、インスリン及び経口血糖降下薬[抗糖尿病薬] | ○手術 | ○ |

図3 収集するDPC情報の項目の概要（イメージ的）

研究成果の刊行に関する一覧

研究成果の刊行に関する一覧表（雑誌）

| 発表者氏名 | 論文タイトル名 | 発表誌名 | 巻号 | ページ | 出版年 |
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研究成果の刊行物・別刷り

Longitudinal Community-Based Assessment of Blood Pressure Control Among Japanese Hypertensive Patients: Fukushima Research of Hypertension (FRESH)

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Seiji Yasumura, MD, PhD¹

In this observational cohort study, the authors assessed the achievement of treatment goals as defined in the Japanese Society of Hypertension's Guidelines for the Management of Hypertension (JSH 2004) among 2743 Japanese hypertensive patients who were followed for 1 year (follow-up rate of 82.6%). Median age was 72 years, and 45% were men. Achievement of treatment goals across all 4 seasons was very low, at 4.1% among patients with diabetes mellitus or renal disease, 3.9% among nonelderly patients (<65 years of age) without these diseases, and 30.8% among elderly patients (≥65 years of age) without these diseases. These findings highlight

the importance of maintaining appropriate blood pressure control. In addition, an analysis of factors associated with achievement rates identified the importance of weight control, lifestyle modification, and family history, and indicated a need for better blood pressure management before complications arise. J Clin Hypertens (Greenwich). 2010;12:166–173. ©2010 Wiley Periodicals, Inc.

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Cardiovascular diseases (CVDs) are some of the most prevalent causes of death globally and are projected to remain the leading cause of death for the foreseeable future.^{1–3} The World Health Organization has reported that 17.5 million persons worldwide are estimated to have died from CVDs in 2005, and an estimated 20 million persons will die from them every year by 2015, mainly from heart attacks and strokes, if corrective action is not taken.⁴ Hypertension is well-known to be one of the most common risk factors for CVDs, which include coronary artery disease, cerebrovascular disease, heart failure, and peripheral artery disease.^{5,6} Up to 30% of adults have high blood pressure (BP) in much of the world, and 50% to 60% of these cases could be prevented by increasing physical activity, maintaining an ideal body weight, and eating a balanced diet.⁷

In the past several decades, many studies have revealed risk factors for hypertension and many

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trials have been conducted in attempts to prevent hypertension and improve BP levels.⁸⁻¹¹ From these studies and trials, several hypertension management guidelines have been established as part of evidence-based manuals, advising health care providers on the most effective and practical therapies for hypertensive patients.¹²⁻¹⁵ Despite these guidelines, however, the prevalence of hypertension is increasing. In the United States, the National Health and Nutrition Examination Survey (NHANES), which was conducted in 1999-2000, reported that the prevalence of hypertension was 28.7% in that period, an increase of 3.7% from 1988 to 1991.¹⁶ Furthermore, the proportion of hypertensive patients whose BP was >140/90 mm Hg remained constant during that time, at 31.0%, although awareness and treatment improved compared with the previous survey. In Japan, the average BP decreased from 1961 to 1990 in men (from 143.2/83.0 mm Hg to 134.3/82.9 mm Hg) and women (from 143.3/82.2 mm Hg to 128.4/77.6 mm Hg) aged 30 to 69 years, likely as a result of public health efforts and newly developed medications.¹⁵ There are still more than 30 million hypertensive patients in Japan,¹⁷ however, and hypertension is the third most common reason for Japanese outpatient clinical visits.¹⁸

Researchers have reported seasonal effects on BP and the incidence and mortality of cerebrovascular disease.^{19,20} A survey of the general Japanese population revealed a significant seasonal pattern in the incidence of intracerebral hemorrhage among patients with hypertension and negative correlations between mean ambient temperature and incidence of both intracerebral hemorrhage and infarction.²⁰ The temperature in Japan varies seasonally, with the average temperature in August reaching approximately 30°C, while in January, the average temperature in Tokyo is approximately 8°C. Based on these previous reports, the importance of controlling BP consistently across all seasons is emphasized in the Japanese Society of Hypertension's Guidelines for the Management of Hypertension (JSH 2004), as well as in other guidelines for hypertension management.¹²⁻¹⁵ A few epidemiologic studies outside Japan have reported success in achieving target BP goals across all seasons,²¹⁻²³ but there is little evidence of this in Japan.

We conducted a prospective study among Japanese hypertensive patients for 1 year. Results from the baseline survey have been previously reported.²⁴ In short, we found a low success rate in achieving treatment goals defined by JSH 2004, and found that obesity, family history, organ damage, and

CVDs were factors that affected this success rate.²⁴ The aim of this report was to assess seasonal changes in the achievement of treatment goals as defined by JSH 2004 and to explore factors associated with success in maintaining BP levels consistently across all seasons.

RESEARCH DESIGN AND METHODS

The present study was a prospective cohort study carried out in Fukushima Prefecture, Japan, from July 2006 to May 2007, and a detailed description is provided in our previous report.²⁴ Participants in our study were hypertensive patients who had been treated with antihypertensive medication for at least 3 months and who visited a participating physician during the baseline survey period (July 2006). Enrolled patients were monitored for 1 year at 3-month intervals (July 2006, October 2006, January 2007, and April 2007).

For the baseline survey, we copied registered patients' clinical data from medical files to survey sheets. Data included age, sex, height, weight, waist circumference, family history (hypertension, diabetes mellitus, dyslipidemia, heart disease, stroke, renal disease, and premature CVD), alcohol consumption, current smoking status, systolic and diastolic BPs, whether the patient had been instructed in home BP measurement, duration of hypertension treatment, usage of antihypertensive drugs, presence of metabolic disorders (diabetes mellitus, dyslipidemia), presence of organ damage, and/or CVD status (brain, heart, kidney, blood vessels, hypertensive, or diabetic retinopathy). We asked physicians to employ their standard methods to measure BP. In general, measurements are taken according to JSH 2004 recommendations in Japan. According to our survey, 80.0% of physicians personally take patient BP measurements, 82.9% do so during medical consultation, 82.9% do so in a consultation room, and 72.9% use a mercury sphygmomanometer. Follow-up surveys collected hypertension-related information, which included whether appointments were kept during the preceding 3-month period, systolic and diastolic BP measurements, and changes in medication.

All data were entered into a computer and analyzed using SPSS version 16 (SPSS Inc, Chicago, IL). We classified patients into 3 groups according to JSH 2004: elderly patients 65 years and older without diabetes mellitus or renal disease, nonelderly patients younger than 65 years without diabetes mellitus or renal disease, and patients with diabetes mellitus or renal disease. We calculated success rates according to the following treatment goals for

Table I. Characteristics of Hypertensive Patients at Baseline

| VARIABLES | MEDIAN (MIN-MAX) OR No. (%) |
|--|-----------------------------------|
| Age, y | 72 (24-99) |
| Sex, male | 1229 (44.8) |
| Anthropometric measurements | |
| Body mass index, kg/m ² | 24.3 (13.2-45.4) |
| Waist circumference, cm | |
| Male | 85.0 (53.0-134.0) |
| Female | 87.5 (59.0-126.0) |
| Family history | |
| Hypertension | 1567 (57.1) |
| Stroke | 796 (29.0) |
| Diabetes mellitus | 476 (17.4) |
| Heart disease | 418 (15.2) |
| Dyslipidemia | 115 (4.2) |
| Renal disease | 99 (3.6) |
| Premature cardiovascular disease | 35 (1.3) |
| Alcohol consumption (daily) | 594 (21.7) |
| Current smoking status | 317 (11.6) |
| Hypertension-related factors | |
| Systolic blood pressure, mm Hg | 134 (84-212) |
| Diastolic blood pressure, mm Hg | 76 (36-124) |
| Instruction in home blood pressure measurement (yes) | 1581 (57.7) |
| Duration of hypertension treatment (yes) | 9.0 (0.5-60) |
| Number of antihypertensive drugs used | |
| 1 | 1219 (44.4) |
| 2 | 1103 (40.3) |
| ≥3 | 421 (15.3) |
| Metabolic disorders | |
| Diabetes mellitus | 834 (30.4) |
| Dyslipidemia | 1211 (44.2) |
| Organ damage/cardiovascular disease | |
| Heart | 538 (19.6) |
| Brain | 368 (13.4) |
| Kidney | 248 (9.0) |
| Peripheral vascular disease | 197 (7.2) |
| Hypertensive retinopathy | 119 (4.3) |
| Diabetic retinopathy | 141 (5.1) |

each group as indicated in JSH 2004: $\leq 140/90$ mm Hg for elderly patients without diabetes mellitus or renal disease, $\leq 130/80$ mm Hg for patients with these diseases, and $\leq 130/85$ mm Hg for nonelderly patients without these diseases. We compared seasonal changes in success rates with baseline data using the McNemar test for each group. For groups in which seasonal change in BP was observed, we displayed the change distribution from the second baseline to the follow-up survey in figures.

To analyze factors associated with failure to achieve treatment goals across all seasons, we first conducted univariate logistic regression analysis. The following independent variables were entered into the analyses: sex, body mass index (BMI), waist circumference, family history, alcohol consumption, current smoking status, instruction in home BP measurement, number of antihypertensive drugs used (1, 2, or ≥ 3), dyslipidemia, and presence of organ damage or CVD. We excluded family history of dyslipidemia, renal disease, and premature cardiovascular death, which were included in JSH 2004, because the incidence of these was very low in our study population. Significant factors from the univariate analysis ($P < .05$) were then entered into a multivariate logistic regression analysis, and odds ratios (ORs) and 95% confidence intervals (95% CIs) were calculated.

This survey was conducted in accordance with Ethical Guidelines for Epidemiological Studies established by the Japanese government,²⁵ and work was performed in accordance with the Helsinki Declaration of 1975 (revised in 2000).²⁶

RESULTS

In the baseline survey, 3358 hypertensive patients were initially registered by 72 of 120 physician members of the Fukushima Hypertension Conference. Thirty-eight of the registered patients were excluded due to missing data on BP or lack of prescribed medications; thus, 3320 patients were entered into the present analysis, and 2743 of them could be followed for 1 year (follow-up rate of 82.6%). Median age of patients was 72 years (24-99 years) and the percentage of men was 44.8% (Table I). Median BMI was 24.3 kg/m² (13.2-45.4 kg/m²), and median waist circumference was 85.0 cm (53.0-134.0 cm) for men and 87.5 cm (59.0-126.0 cm) for women. For family history, prevalence of hypertension was most frequent (57.1%), followed by stroke (29.0%), diabetes mellitus (17.4%), and heart disease (15.2%). Prevalence of alcohol use (daily consumption) was 21.7%, and 11.6% were current smokers. Median systolic and diastolic BPs were 134 mm Hg (84-212 mm Hg) and 76 mm Hg (36-124 mm Hg), respectively. Fifty-eight percent of patients were given instructions on how to measure their BP at home, 44.4% of patients were treated with 1 antihypertensive drug, and the median duration of hypertension treatment was 9.0 years (0.5-60.0 years). Proportion of those with diabetes mellitus was 30.4%, and 44.2% had dyslipidemia. Cardiovascular complications were reported in 19.6% of patients,

neurological complications in 13.4%, and renal complications in 9.0%.

Table II shows changes in success rates in achieving BP goals (defined by JSH 2004) across all seasons. Among elderly patients without diabetes mellitus or renal disease, the success rate significantly dropped from 65.9% to 61.6% in January 2007 compared with baseline (July 2006). Figure 1 shows the distribution of changes in systolic BPs of elderly patients without diabetes mellitus or renal disease. Mean change was 1.43 mm Hg (standard deviation [SD] 15.69 mm Hg) ranging from -68 mm Hg to 66 mm Hg. Also, Figure 2 shows the distribution for diastolic BPs, and mean change was 0.54 mm Hg (SD 9.93 mm Hg) and ranged from -36 mm Hg to 46 mm Hg.

Among elderly patients without diabetes mellitus or renal disease, 30.8% were successful in achieving their BP goals across all seasons, while 9.4% were unsuccessful. In contrast, for nonelderly patients without these diseases, year-round success and failure rates were 3.9% and 42.9%, respectively, and for patients with these diseases, year-round success and failure rates were 4.1% and 45.5%, respectively (Table III).

Multivariate analysis showed that factors significantly associated with all-season failure to achieve treatment goals in elderly patients without diabetes mellitus or renal disease were the use of ≥ 2 antihypertensive drugs (OR, 2.08; 95% CI, 1.34-3.25 and OR, 4.45; 95% CI, 2.68-7.40), and the presence of organ damage or CVD (OR, 0.55; 95% CI, 0.36-0.84) (Table IV). For nonelderly patients without these diseases, significant factors associated with all-season failure to achieve goals were male sex (OR, 0.63; 95% CI, 0.43-0.92), BMI ≥ 25 kg/m² (OR, 2.11; 95% CI, 1.44-3.07), and presence of organ damage or CVD (OR, 0.47; 95% CI, 0.28-0.79) (Table IV). For patients with these diseases, a family history of hypertension (OR, 1.40; 95% CI, 1.07-1.83), daily alcohol consumption (OR, 1.64; 95% CI, 1.15-2.32), current smoking status (OR, 1.53; 95% CI, 1.02-2.30), receiving instruction in home BP measurement (OR, 1.41; 95% CI, 1.07-1.86), dyslipidemia (OR, 1.35; 95% CI, 1.07-1.77), and presence of organ damage or CVD (OR, 0.58; 95% CI, 0.44-0.76) were significantly associated with year-round failure to achieve treatment goals (Table IV).

We performed a power calculation for the presence of organ damage or CVD, which was a significant factor in all subgroups, and estimated the power as 98.3%.

| | ELDERLY PATIENTS WITHOUT DIABETES MELLITUS OR RENAL DISEASE (N=1319) | | | NONELDERLY PATIENTS WITHOUT DIABETES MELLITUS OR RENAL DISEASE (N=482) | | | PATIENTS WITH DIABETES MELLITUS OR RENAL DISEASE (N=942) | | |
|---------------------------------|--|------------|----------------------|--|------------|----------------------|--|------------|----------------------|
| | MEAN (SD) SBP/DBP, MM Hg | NO. (%) | P VALUE ^a | MEAN (SD) SBP/DBP, MM Hg | NO. (%) | P VALUE ^a | MEAN (SD) ^b SBP/DBP, MM Hg | NO. (%) | P VALUE ^a |
| Baseline (July 2006) | 134.1 (13.5)/74.5 (9.0) | 869 (65.9) | | 133.2 (12.5)/80.2 (8.7) | 141 (29.3) | | 135.4 (14.1)/75.5 (10.5) | 231 (24.5) | |
| First follow-up (October 2006) | 134.3 (13.2)/74.6 (9.1) | 874 (66.3) | .89 | 134.7 (12.9)/81.2 (8.6) | 119 (24.7) | .07 | 135.3 (14.6)/75.5 (9.7) | 229 (24.3) | 1.00 |
| Second follow-up (January 2007) | 135.5 (14.0)/75.0 (9.4) | 813 (61.6) | .01 | 135.0 (13.3)/80.7 (9.4) | 117 (24.3) | .07 | 136.1 (15.6)/75.4 (10.6) | 242 (25.7) | .55 |
| Third follow-up (April 2007) | 135.3 (13.6)/75.0 (9.2) | 830 (62.9) | .08 | 134.1 (12.5)/80.8 (9.1) | 142 (29.5) | 1.00 | 135.5 (14.8)/75.5 (10.9) | 249 (26.4) | .30 |

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation. ^aSeasonal changes in success rates were compared with the McNemar test baseline data in each group.

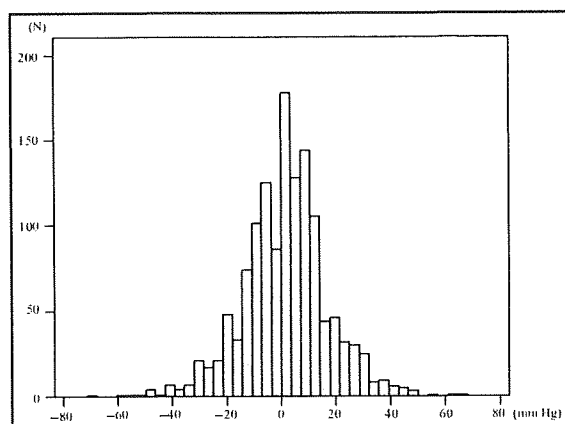


Figure 1. Distribution of changes in systolic blood pressure between measurements between second follow-up and baseline survey among elderly patients without diabetes mellitus or renal disease.

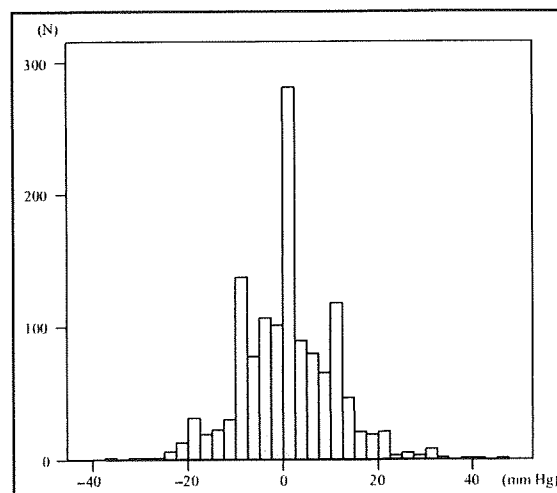


Figure 2. Distribution of changes in diastolic blood pressure between measurements between second follow-up and baseline survey among elderly patients without diabetes mellitus or renal disease.

DISCUSSION

To the best of our knowledge, this is the first Japanese community-based prospective study evaluating hypertension treatment according to JSH 2004 guidelines. Overall results seemed to show excellent control of BP with a median BP <140/90 mm Hg throughout the year. However, in terms of JSH 2004 treatment goals, all-season success rates were extremely low in nonelderly Japanese hypertensive patients without diabetes mellitus or renal disease and in all patients with these diseases. In our previous report analyzing baseline survey data obtained in the summer,²⁴ we reported low rates of success in achievement of BP goals among nonelderly without diabetes mellitus or renal disease and among patients with these diseases. Adding to these findings, the proportion of patients who had success across all seasons in the present follow-up survey was as low as 5% in nonelderly without diabetes mellitus or renal disease as well as in patients with these diseases, highlighting the difficulty in consistently maintaining BP in these patients. Furthermore, success rates showed statistical significance, but the slight drop during the winter among elderly patients without diabetes mellitus or renal disease indicates that ambient temperature may be an important factor in the management of hypertension among these patients. A number of studies have shown that BP is subject to seasonal influences and is lower in hot seasons than in cold ones.²⁷⁻³⁰ A population-based prospective study among the elderly reported that outdoor temperature and BP levels were strongly correlated.³⁰ Accordingly, cardiovascular events are known to occur at a higher rate in winter.^{19,20,31} In addition, as vitamin

D deficiency is known to lower BP, and may occur in winter due to reduced sun exposure, this may explain some seasonal changes in BP levels.³² In the present study, seasonal variation was observed only among elderly patients without diabetes mellitus or renal disease. It is possible that these patients may be more vigilant in maintaining their BP in the winter compared with patients without these diseases, and their attending doctors may be more aggressive in their treatment of these patients. These results indicate that clinicians and patients should pay greater attention to BP maintenance during cold seasons.

Further multivariate analysis revealed factors associated with all-season failure to achieve BP goals. It is noteworthy that these risk factors were different in each group. Among elderly patients without diabetes mellitus or renal disease, the only risk factor was an increased number of medications. We propose two possible explanations for this. For one, these elderly patients without diabetes mellitus or renal disease may have fewer risk factors such as obesity, family history, and lifestyle factors, which may have played a role in the multivariate analysis of the other two groups. One of our previous studies conducted in a Japanese community showed that elderly patients had healthier lifestyles and a lower proportion of obesity compared with nonelderly patients.³³ Another possible explanation is that physicians may be more careful in adding medications for elderly patients due to their known susceptibility to variability in BP and widening of pulse pressure.¹⁵ Accordingly, in our

| | YEAR-ROUND FAILURE, NO. (%) | YEAR-ROUND SUCCESS, NO. (%) |
|--|-----------------------------|-----------------------------|
| Elderly patients without diabetes mellitus or renal disease (n=1320) | 124 (9.4) | 407 (30.8) |
| Nonelderly patients without diabetes mellitus or renal disease (n=482) | 207 (42.9) | 19 (3.9) |
| Patients with diabetes mellitus or renal disease (n=941) | 429 (45.5) | 39 (4.1) |

| SIGNIFICANT VARIABLES | NO. (%) | ODDS RATIO | 95% CONFIDENCE INTERVAL | P VALUE |
|--|------------|------------------|-------------------------|---------|
| Elderly patients without diabetes mellitus or renal disease | | | | |
| No. of antihypertensive drug used | | | | |
| 1 | 632 (47.9) | 1.00 (Reference) | | |
| 2 | 508 (38.5) | 2.08 | 1.34–3.25 | <.01 |
| ≥3 | 180 (13.6) | 4.45 | 2.68–7.40 | <.01 |
| Presence of organ damage or cardiovascular disease | 475 (36.0) | 0.55 | 0.36–0.84 | <.01 |
| Nonelderly patients without diabetes mellitus or renal disease | | | | |
| Sex (male) | | | | |
| | 274 (56.8) | 0.63 | 0.43–0.92 | <.01 |
| Body mass index ≥25 kg/m ² | | | | |
| | 204 (42.6) | 2.11 | 1.44–3.07 | <.01 |
| Presence of organ damage or cardiovascular disease | 88 (18.3) | 0.47 | 0.28–0.79 | <.01 |
| Patients with diabetes mellitus or renal disease | | | | |
| Family history of hypertension (yes) | | | | |
| | 508 (53.9) | 1.40 | 1.07–1.83 | <.01 |
| Alcohol consumption (daily) | | | | |
| | 175 (18.7) | 1.64 | 1.15–2.32 | <.01 |
| Current smoking status | | | | |
| | 128 (13.6) | 1.53 | 1.02–2.30 | <.01 |
| Hypertension-related factors | | | | |
| Instruction in home blood pressure measurement (yes) | | | | |
| | 560 (59.6) | 1.41 | 1.07–1.86 | <.01 |
| Dyslipidemia (yes) | | | | |
| | 511 (54.4) | 1.35 | 1.03–1.77 | <.01 |
| Presence of organ damage or cardiovascular disease | | | | |
| | 459 (48.8) | 0.58 | 0.44–0.76 | <.01 |

study, median BP of elderly patients without diabetes mellitus or renal disease treated with ≥2 medications was significantly higher than in nonelderly patients without these diseases. The proportion of patients with diastolic BPs <60 mm Hg was also significantly higher among elderly patients than nonelderly patients.

As for the nonelderly group without diabetes mellitus or renal disease, female sex and BMI >25 kg/m² were major risk factors. For sex-specific BP control, NHANES 1999–2004³⁴ reported that the proportion of men with uncontrolled BP was 50.8% and for women was 55.9%. The most recent survey indicated that hypertension medications were prescribed more often for men than for women, which was consistent with our survey. Sex hormones may also contribute to the sex-specific differences in BP control. Androgen, for example, may be a major contributor toward increases in BP among postmenopausal women.³⁵

As for obesity, it has been clearly demonstrated that BMI is positively associated with high BP.^{36–39} The Atherosclerosis Risk in Communities (ARIC) study³⁸ has shown that weight gain leads to increased systolic and diastolic BP levels. Assessment of sex-specific characteristics and body weight should be recognized as important factors for the management of hypertension among nonelderly patients.

Several factors were associated with high BP in patients with diabetes mellitus or renal disease: family history, health habits, and metabolic variables were shown to be risk factors by multivariate regression analysis. The relationship between hypertension and a family history of this disease has been previously reported,^{40–42} and genetic, biochemical, and behavioral components are implicated in this relationship.⁴² Dekkers and colleagues⁴⁰ reported that a family history of essential hypertension was associated with increased systolic BP and formation of left ventricular mass in childhood. As for health habits, daily alcohol consumption and

current smoking status increased the risk of failure to achieve BP goals. Excessive intake of alcohol and smoking are well-known to increase BP, and restriction of these habits is recommended in hypertension management guidelines.^{12-15, 43-46} Dyslipidemia is frequently observed in hypertensive patients and should be considered as an important factor for hypertension treatment, as stated in the guidelines.¹²⁻¹⁵ Our present results indicate the importance of assessing family history and making lifestyle modifications for better management of hypertension among patients with diabetes mellitus or renal disease.

Interestingly, we found a positive association between history of organ and vascular complications and year-round achievement of BP goals in all groups. This seemingly paradoxical result may be due to increased awareness in managing BP levels by both doctors and patients once a complication occurs. A previous study has pointed out that a lack of disease awareness is a patient-related factor associated with poor BP control.⁴⁷ Our study provides an important indication of the necessity of appropriately managing hypertension by both physicians and patients prior to the onset of complications.

LIMITATIONS

The first limitation of our study was selection bias. Physicians who participated in our study were all members of the Fukushima Hypertension Conference, and the number of patients was reduced from 3320 to 2743 during the follow-up period. It is possible that participating physicians and patients might be more aware of hypertension management practices compared with nonparticipants. Success rates might be lower if nonparticipants were included. Second, some important factors, such as the patients' health behavior and disease awareness, and physician's awareness and daily practices, were not obtained in our survey. Inclusion of these additional factors in the multivariate analysis model might have altered our results. Use of multiple medications and instruction in home BP measurement were found to be risk factors. Without more detailed data about physicians in our study, we are unable to determine whether results reflect inadequacies in physicians' oversight of medication regimens and instruction in home monitoring in patients with poor control, or whether poor control is a direct result of multiple medications and home monitoring.

CONCLUSIONS

The present cohort study revealed low success rates in achieving treatment goals for hypertensive

patients during 1 year, especially in patients with diabetes mellitus or renal disease, and patients younger than 65 years without these diseases. Analysis of associated factors indicated the importance of weight control for nonelderly patients without diabetes mellitus or renal disease, lifestyle modification, family history assessment for patients with these diseases, and better BP management before atherosclerotic complications arise for all hypertensive patients.

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Gaps Between Hypertension Treatment Guidelines and Clinical Practice in Japan: Baseline Survey Results From Fukushima Research of Hypertension (FRESH)

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This observational study assessed the achievement of treatment goals, as defined by the Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2004). These goals are: <140/80 mm Hg in elderly patients (65 years and older), <130/80 mm Hg in patients with diabetes or kidney disease, and <130/85 mm Hg in younger patients (younger than 65). From July 2006 to May 2007, 72 physician members of the Fukushima Hypertension Conference enrolled a total of 3320 patients from Fukushima Prefecture, Japan. The median age of the patients was 71 years and 46% were male. The success rate was 27% among patients with diabetes mellitus or renal disease, 30% among those younger than 65 years, and 66% among the elderly without the diseases. Factors

significantly associated with an increased risk of failure to achieve goals were obesity, dyslipidemia, family histories of diabetes mellitus or hypertension, and number of antihypertensive drugs used. The presence of atherosclerotic complications decreased the risk. This study revealed low achievement rates, identified the importance of weight control and family histories, and indicated a need for better management to prevent complications. J Clin Hypertens (Greenwich). 2009;11:333–341. ©2009 Wiley Periodicals, Inc.

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According to the World Health Organization (WHO),¹ reported cardiovascular disease (CVD) was the most common cause of death worldwide in 2005, accounting for approximately 30% of all deaths, with the main causes of death among individuals 60 years and older being ischemic heart disease followed by cerebrovascular disease.² Prevention of CVD is emphasized in both developed and developing countries.^{1,2} Hypertension affects approximately 1 billion people worldwide³ and is estimated to account for 6% of deaths worldwide.⁴ It is among the most important modifiable risk factors for CVD, and also the most common reason for outpatient office visits to physicians.⁵

Hypertension management consists of several components, including the screening of elevated blood pressure (BP), lifestyle interventions and evaluation for pharmaceutical treatment, continued

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