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Thesis:

Hypertension Case Management in Yerevan Ambulatory Settings

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CONTENTS

ABBREVIATIONS

CVD	**Cardiovascular Disease**
HCM	**Hypertension Case Management**
CHD	**Coronary Heart Disease**
HYP	**Hypertension**
MI	**Myocardial Infarction**
SBP	**Systolic Blood Pressure**
DBP	**Diastolic Blood Pressure**
JNC	**US Joint National Committee on Hypertension**
LVH	**Left Ventricular Hypertrophy**
OR	**Odds Ratio**
CI	**Confidence Interval**

Abstract

Hypertension is one of the major contributors to atherosclerotic cardiovascular disease, the leading cause of death in Armenia. Hypertension case management patterns have significantly changed over the last decades. An early detection and lifelong hypotensive therapy have been proved to be critical in the prevention of hypertension-related adverse outcomes, such as cardiac failure, stroke, coronary heart disease, and peripheral artery disease. This study is a pilot study attempting to assess relationships between the quality of hypertension case management by primary health care providers in Yerevan, Armenia and hypertension-related adverse outcomes.

Study design: case-control unmatched study.

Setting: community-based primary health center (district policlinic) in Yerevan, Armenia.

Data source: records in ambulatory medical charts of stroke and non-stroke hypertensive patients.

Sampling: all available cases and controls in the policlinic purposively selected of 28 located in Yerevan.

Population: cases were defined as ambulatory patients with first-ever stroke developed in the period of time from January to July of 1997 who had previously diagnosed hypertension. Controls were defined as ambulatory hypertensive patients without stroke who applied for physician home visit because of hypertension during the same period of time. Cases and controls were identified through multiple administrative data sources.

Analysis: the assessment of management of hypertensive patients prior to stroke (for controls - prior to a home visit) was done on the base of scored checklist. Criteria for the assessment of hypertension case management were established on the basis of literature review and the local protocols. All items were equally weighted in the checklist. Number of fulfilled criteria was characterized as hypertension case management (HCM) adherence scores. Depending on the adherence scores calculated for each of cases and controls, HCM was classified as "fair" or "poor".

Results: no statistically significant differences were detected in the management of patients in the case and control groups except for the patients aged over 60 years. These results concur with the meta-analysis of randomized studies in which greater benefits of hypertensive treatment were detected in elderly patients.

Introduction

Background: Hypertension, a "silent killer", is characterised by the often asymptomatic advancement of disease and its life-threatening outcomes. It was shown in the follow up of Framingham Study that hypertension is one of the major contributors to atherosclerotic cardiovascular disease (CVD), which includes cardiac failure, stroke, coronary heart disease, and peripheral artery disease[1]. Hypertension contributes to cardiovascular disease morbidity and mortality along with the other risk factors for cardiovascular disease, such as smoking, dyslipidemia, insulin resistance, glucose intolerance, and obesity[1]. Depending on the number of risk factors, the risk of major cardiovascular events may increase from 2 to 8 fold [2]. Coronary heart disease is the most common and lethal adverse outcome of hypertension, while stroke has higher disability rates[2].

A dramatic decline in cardiovascular mortality has been observed over the past 20 years in US as a result of public health initiatives, such as control of hypertension, antismoking campaigns, and lifestyle modifications[3]. On the contrary, the burden of cardiovascular diseases in the Orient, particularly in China and Russia (former Soviet Union) has not show any improvement[4,5,6]. Cardiovascular disease remains the leading cause of death in Armenia. Deaths from circulatory system diseases comprised 52.3% of all causes of death in Armenia [7]. According to the World Bank report on poverty issues in Armenia, the incidence of circulatory diseases in Armenia increased to 339 per 100,000 in 1994 from 297

in 1989 [8]. Statistics obtained from the National Health Information-Analytic Center confirm the high mortality rates from cardiovascular diseases in Armenia (Figure 1).

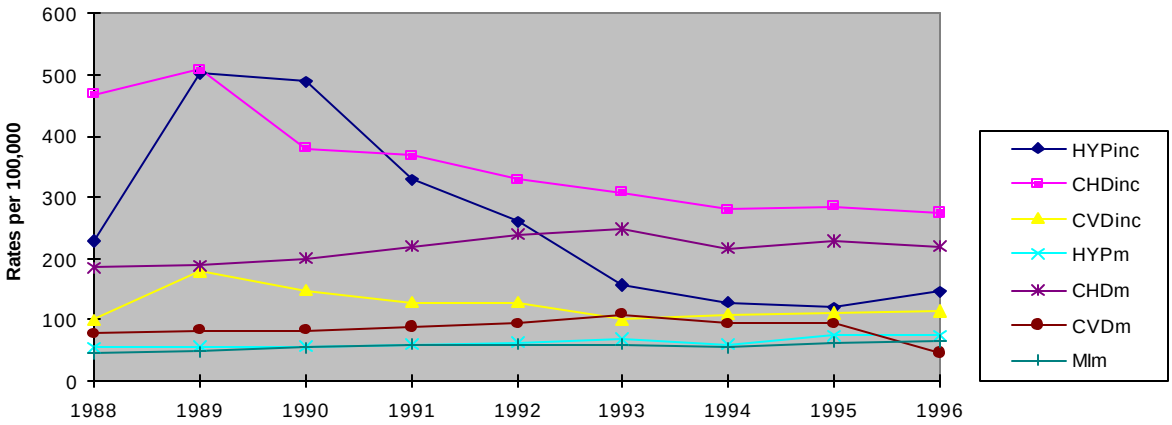

Figure 1. Cardiovascular disease incidence and mortality rates in Armenia 1988-1996.
Source: National Health Information-Analytic Center

Neverthel he burden of non-communicable diseases i expenditures. Only 13% of total health expenditures were devoted to the public health, and only about 5% of the latter was allocated to the public health expenditures on non-communicable diseases [8].

Literature review: The literature search using Medline from 1990 to 1996 references from meta-analysis of randomised controlled trials has confirmed the benefits of treatment in prevention of hypertension-related outcomes, such as myocardial infarction (MI) and stroke [9,10]. The antihypertensive treatment was more effective in the elderly compare to younger patients in the randomised SHEP[1] study [11].

Hypertension control rates all over the world remain low despite of increased hypertension detection and awareness and the availability of new highly effective antihypertensive drugs[12,13]. The proportion of patients with controlled hypertension varied from 17.5% to 84.6% when assessment was done with different guidelines [13. According to literature, hypertension control rates are lower among groups of population with lower socio-economic status. Lack of access to the health care was an important predisposing factor for uncontrolled hypertension[12].

Nevertheless, according to Stockwell, even in the absence of financial barriers with full access to the care and covered cost of treatment, hypertension control rates remain low[12]. This suggests that a continuing improvement in the management of hypertension may be a useful strategy rather than more intensive screening for detection. Thus, the problem of hypertension-related adverse outcomes directly relates to the quality of medical care [12].

Quality of ambulatory care assessment tools: To assess the quality of care, performance indicators are used as indirect measures of quality. Hypertension is among those conditions for which data collection protocols have been already developed and tested[14]. An important claims-based tool for the measurement of quality of ambulatory care was established in the Develop and Evaluate Methods To

[1] Systolic Hypertension in the Elderly Program.

Provide Ambulatory Quality (DEMPAQ) project [14]. Hypertension specific DEMPAQ Records set involves:

- appropriate evidence for a new diagnosis of hypertension
- appropriate prescription of alpha blocker
- appropriate prescription of calcium channel blocker
- appropriate prescription of different types of diuretics
- BP measurement every six months
- document diet every six months
- document drug compliance every six months
- pulse measurement every six months
- yearly heart/lung exam
- yearly fundoscopy
- yearly U/A dipstick for protein
- yearly weight measurement
- search for treatable causes of a new diagnoses of hypertension [15].

According to Kazandjian, a performance assessment system should satisfy several criteria, including use of both process and outcome measures and multiple data sources [14]. The three most common sources of data are administrative data, medical records, and patient surveys. Administrative data, especially record-based data, have limitations: the accuracy and validity of records may be insufficient, and audit is time and labour consuming [14]. The feasibility of use of standardised self-administrated questionnaires as data collection tools for patient outcomes has been documented in the Medical Outcomes Study [16]. In another study, expert opinion has been used to assess provider performance against standards of detection and management of hypertension through the audit of avoidable deaths from hypertension and stroke [17].

In the study of the relation of various process items and the outcome for hypertensive patients treated in Mayo Clinic (Rochester, MN), no statistically significant association was detected between process of care (a rigid list of process items was used as a checklist) and outcome of care (different categories of BP) [18]. In another study, it was found that more frequent visits to physician did not correspond to more satisfactory control of blood pressure. The only measure associated with hypertension control was the amount of medication taken, without any correlation the number of visits [12].

The latest investigations have recognised the role of outcome-oriented methods as a primary standard for the measurement of quality of care[3,5]. Not only distinct studies used the outcome-based approach for evaluation of hypertension treatment, but also the Joint National Committee on Hypertension 5th Report stated the outcome-oriented rationale for the initial choice of antihypertensive therapy. Specifically, only those classes of antihypertensive drugs were recommended as a first choice in the management of hypertension, for which the reduction of hypertension-related morbidity and mortality was shown in randomised placebo-controlled clinical trials[3].

Study aim: This study is an attempt to assess the relationships between the quality of ambulatory care in hypertension case management in Yerevan, Armenia and hypertension-related adverse outcome. Ambulatory care plays an important role in HCM. According to Price D.W., hypertension is one of the most common reasons for visits to family physician[9]. Based on the reviewed literature , he suggested that a non-pharmacological treatment approach to the hypertensive patients may be more cost-effective, especially when other cardiovascular risk factors are present. Further research on outcomes and cost-effectiveness of care was suggested for the improvement of the hypertension management. Our study, designed as a case-control, was aimed at the assessment of hypertension case management in stroke

patients as compared to the care of hypertensives who have not developed stroke. An outcome-based approach was used in the study to assess the effects of quality of HCM on the related adverse outcomes. Stroke was chosen as an outcome for the assessment of HCM because of its high risk in hypertensive patients. The assessment was done on the basis of patient record review in the primary health care setting. A checklist for records audit was developed from the literature review and the existing ambulatory patients management protocols[19]. The objective of this study was to measure the extent of adherence to the established criteria for hypertension ambulatory treatment and determine whether "better" care reduced the risk of stroke.

Methodology of the Study

The major research question to be addressed by the study was as follows:

Research Question**:** What are the hypertension case management (HCM) patterns in stroke patients with previously detected hypertension in ambulatory health care settings in Yerevan, Armenia and how do they compare to the HCM in the hypertensive patients without stroke?

Null Hypothesis Ho**:** HCM patterns in ambulatory health care settings in Yerevan, Armenia in stroke patients with previously detected hypertension and hypertensive patients who have not suffered a stroke do not differ.

Alternative Hypothesis H_A: HCM patterns in ambulatory health care settings in Yerevan, Armenia in stroke patients with previously detected hypertension are different as compared to HCM in hypertensive patients who have not suffered a stroke.

Study design is an unmatched case-control method applied for the evaluation of quality of ambulatory care. Quality of ambulatory health care for hypertension was evaluated through a review of the records

of all stroke patients with previously recorded hypertension in a district policlinic in Yerevan, Armenia. Only one out of 28 community-based policlinics located in Yerevan was selected for the study due to limited time and resources. One of the central top-ranked policlinics was purposively selected to conduct the study under the best conditions. The main approaches of this study may be used for the evaluation of quality of care regarding not only to hypertension but any other ambulatory conditions. In fact, case-control is the best possible design for the assessing the impact of process of care on the rare health outcome, such as stroke[20,21]. Such a design was suitable not only conceptually but also because of the limited time and other resources.

Setting: The policlinic has 18 district physicians and various specialists. It is relatively well equipped and provides ambulatory services to about 30,000 adults. The study may be considered as a pilot study before the implementation of a broader evaluation of the quality of care.

Case definition was developed from a review of the literature from 1977 to 1996 and revised during the pre-test. Cases were defined as patients who developed first-ever fatal or non-fatal stroke in the period of time from January to July of 1997 and had previously recorded hypertension in ambulatory charts. The diagnosis of stroke was considered justified if the diagnosis was made either in the hospital or by a qualified neurologist from the policlinic. The patients with transient cerebrovascular accidents and recurrent strokes were excluded from the review.

Controls were defined as patients with recorded hypertension in the ambulatory medical chart for whom a physician home visit was made because of hypertension in the period of time from January to July of 1997. It seems reasonable to select as controls the patients who had experienced a kind of hypertensive emergency (when applied for a physician home visit) in the same period of time when cases had

developed stroke. Non-stroke patients with newly diagnosed hypertension in the specified above period of time, were excluded from the review because it was not possible to assess all categories of HCM.

Cases and controls were defined as having hypertension if the following was recorded at least one time in the ambulatory chart:

1) a systolic blood pressure (SBP) equal to 140 mmHg or higher,

2) or / and a diastolic blood pressure (DBP) equal to 90 mmHg or higher was recorded at least one time in the ambulatory chart.

The cutpoints mentioned above are not the most conservative approach for the definition of hypertension (for example, the British Hypertension Committee's Guidelines suggest higher levels of blood pressure as criteria). Nevertheless, it is reasonable, because the same criteria have been used in Armenia for the last decades.

Methods of ascertainment of cases and controls. Cases were ascertained through the multiple sources:

1. The administrative data of home visits made by policlinic neurologists in the period of time from January to July of 1997.

2. The registered admissions to the neurological department of the 2nd Yerevan Hospital in the period of time from January to July, 1997 (the department operates as a co-partner of the mentioned policlinic).

3. The death certificate registrar book of the policlinic.

The list of non-stroke comparison patients was identified according to the diagnosis of hypertension registered in the home visits registrar book of the policlinic. All the patients with diagnosed hypertension and available medical charts, for whom home visit was made by one of the 18 physicians of the policlinic, were eligible for the records review. Such method of ascertainment of non-stroke patients, based on

home visits, was chosen due to the sharp decline in utilization of ambulatory services and unavailability of data on office visits in the specified period of time.

Data collection. The majority of the medical charts of the identified stroke and non-stroke patients were available for audit in the registrar department of the policlinic, namely 83% (25/30) of patients with stroke and 75% (33/45) of hypertensives without stroke. The charts were first reviewed for the eligibility to be included in the study. 4 stroke patients were miscoded (2 cases of recurrent stroke, 1 case of transient accident and 1 case had developed first-ever stroke in the time period other than specified above). Two non-stroke patients with newly diagnosed hypertension did not met eligibility criteria. In total, records of 21 stroke cases with previously detected hypertension and 31 non-stroke hypertensive controls met our criteria and were included in the study.

Hypertension case management assessment checklist. The assessment of the recorded hypertension case management in the stroke and non-stroke patients was based on the same criteria. These criteria were developed on the basis of literature review and the existing protocol. They were included in the HCM checklist and revised during the pre-test. The criteria for the assessment of hypertension case management were grouped into several categories, namely medical history, cardiovascular risk factors, physical examination, laboratory tests, referrals, follow up, non-pharmacological and pharmacological treatment, and comorbidities. Not all the categories were scored; particularly, the pharmacological treatment items where classes of antihypertensive medications for which the appropriateness of prescription was difficult to evaluate. That is why the treatment preferences among primary health providers will be discussed separately in the analysis of data. The category of comorbidities also was not scored, but used for the analysis. The criteria are presented below:

Table 1. Categories of HCM assessment checklist[2].

[2] see Appendix.

#	Category	Item	#	Category	Item
1.	Medical history	complaints history of vitae history of disease family history	5.	Referrals	EKG fundoscopy neurological exam
2.	CV risk factors	non specified smoking overweight lifestyle alcohol use	6.	Non-pharmacological treatment	not specified diet exercise weight control alcohol intake limitation smoking cessation
3.	Physical exam	heart exam pulse exam lung exam	7.	Follow up	# of visits in the first year # of BP measurement in the first year lost to follow up follow up date recorded
4.	Laboratory tests	blood test urine test total cholesterol	8.	Comorbidities	diabetes ischemic heart disease congestive heart disease obstructive pulmonary disease asthma prostatic hypertrophy other

Statistical analysis. The analysis of review of 52 records was done with a computerized statistical program Epi5. As an explicit "standard" for hypertensive patient management in ambulatory setting, a 30 items scored checklist for the adherence to the established categories of process was used. All the 30 items were equally weighted (1 item = 1 point). Since the distribution of these scores within the groups were not normal, it was not appropriate to apply a t-test to test the null hypothesis. Instead, a categorical type of HCM variable was considered. The HCM scores of eighteen (out of the possible 30) were set as 60% cutpoint. The management of hypertension in stroke and non-stroke patients was considered "fair" if the adherence scores were equal to 18 or higher, and "poor" if they were less than 18.

Sample size. In the study, sample size was limited to the number of all available cases (21). All the patients satisfied the criteria for selection of controls (31) were included in the study to increase power. If

the expected frequency of "fair" management differs significantly (0.4) in the case and control populations, then the power of unmatched case-control study is about 80% to detect such differences (Table2). If differences in two populations are smaller (0.16), the statistical test performed has about 25% power to detect that differences. For the further increase of the power of the test, the study design should be changed to have a larger number of cases and/or controls. A broader study in randomly selected policlinics may increase not only the power of the test, but more importantly, achieve higher generalizibility of the results.

Table2. Power of the study for different frequencies of "fair" management in stroke and non-stroke populations [3].

Differences in the expected frequency of "fair" management in two groups	Power of the study %	Confidence level %
0.4	80	90
0.3	45.5	95
0.16	25	90

Results

Demographic characteristics. As it is shown in the Table 3., the cases and control groups were not homogenous with regard to age and gender. Mean age of the cases was 71.4 years with the range 55 to 83 years. Mean age in control group was 61.6 with the range 36 to 84 years. Stroke patients were on average 10 years older that non-stroke patients. Statistically significant differences (p=0.006) were detected between the groups with regard to the number of older patients. Also, there were significant differences (p=0.005) in the gender composition of the groups: male patients were more prevalent in the stroke group than in the non-stroke group. These differences were taken into account in the analysis of the data.

Clinical characteristics (Table 3). Systolic and diastolic blood pressure means were almost the same in both groups at initial visit. To assure comparability of the case and control groups, a stratification[4] by the severity of hypertension was done. No statistically significant differences were detected in the groups of stroke and non-stroke patients by systolic and diastolic blood pressure levels at initial visit. There were no statistically significant differences with regard to the presence of comorbidities in stroke and non-stroke patients. Taking into the consideration the literature data on higher stroke risk in hypertensives with diabetes, the differences for coexisting diabetes were assessed separately. No statistically significant differences were detected in these groups of patients.

Distribution of the HCM scores: To test the null hypothesis, the total scores for hypertension management in case and control groups were analysed using bivariate technique. If the null hypothesis were true, then stroke patients were managed by health care providers with the similar HCM scores as controls. If the alternative hypothesis were true, then the stroke patients should be managed with the lower

Table 3. Demographic and clinical characteristics of stroke and non-stroke groups.

Characteristics	Cases (n=21)	Controls (n=31)	p-value
Age (mean), yr. ± sd	71.4 ± 9.1	61.6 ± 12.8	_
Age ≥ 60			**0.006**
	19 (90%)	17 (55%)	**7.8 (1.36<OR<58)**
Gender (male)			**0.005**
	11 (52%)	5 (16%)	**5.72 (1.35<OR<25)**
SBP at initial visit (mean)			_
mmHg	158.6 ± 18.2	158.6 ± 22.7	

[3] EpiInfo6 Statcalc program was used.
[4] Strata defined according to JNC-5 Report. Severe and very severy hypertension strata were combined due to small group size.

SBP at initial visit				0.5
mmHg	130-159	9 (43%)	16 (52%)	0.7 (0.2<OR<2.4)
				0.6
	160-179	10 (48%)	13 (42%)	1.2 (0.3<OR<4.5)
				0.6
	180>	2 (9.5%)	2 (6.5%)	1.5 (0.1<OR<17)
DBP at initial visit (mean)				–
mmHg	130-159	89.8 ± 7.2	94.2 ± 12.5	
DBP at initial visit				0.6
mmHg	80-99	15 (71%)	20 (65%)	1.3 (0.3<OR<5)
				0.8
	100-109	5 (24%)	8 (26%)	0.9 (0.2<OR<3.8)
				0.5
	110-140	1 (4.8%)	3 (9.7%)	0.4 (0.02<OR<5.7)
				0.08
Comorbidities[5] present		17 (82%)	18 (58%)	3.07 (0.72<OR<13.9)
Diabetes		3 (14%)	1 (3%)	5.0 (0.41<OR<135)

scores as compare to controls. 80.9% (17) of stroke cases and 64.5% (20) of non-stroke controls were considered as "poorly" managed since their HCM total scores were lower than 60% cutpoint. Bivariate analysis was done for the subgroups with "fair" and "poor" management of hypertension in cases and controls. There were no statistically significant differences (p=0.05) between cases and controls by HCM total scores:

Table 4. HCM total scores by groups.

Total scores	Cases (n=21)	Controls (n=31)	OR with 95% CI

[5] If any of the following was present: diabetes, ischemic heart disease, obstructive pulmonary disease, astma, prostatic hypertrophy, and other diseases.

scores ≥ 18	4	11	0.43
scores< 18	17	20	(0.08<OR<1.82)

In addition to the analysis of total HCM adherence scores, a bivariate technique was applied to the different categories of the hypertension case management process.

Table 5. HCM scores by the categories of process in stroke and non-stroke groups.

Categories	Cases (n=21)	Controls (n=31)	OR with 95% CI
Laboratory tests (at least 2)	11	20	0.6 0.17<OR<2.16
Referrals (at least 2)	3	10	0.35 0.06<OR<1.71
No advise given on non-pharmacological treatment	18	18	4.33 0.91<OR<23.2
No treatment at initial visit	11	6	**4.58** 1.14<OR<19.2
at last visit	12	4	**9.00** 1.97<OR<44.9
Follow up visits ≥ 2 in first year	14	21	0.95 0.25<OR<3.64

No statistically significant differences were detected except for the absence of a pharmacological treatment (Table 5). The odds ratio of developing a stroke was accordingly 4.6 and 9 times higher for the patients for whom no pharmacological treatment was recorded at initial and last visits.

However, these results have to be adjusted for the differences in composition of two groups. The cases and the controls were not similar with respect to gender and age. These characteristics may have a confounding effect due to the association not only with stroke, but also with the hypertension management

process. To adjust for the above mentioned confounder variables, a stratification by age and gender was done. After the adjustment, the following results were obtained:

Table 6. Distribution of total HCM adherence scores by age and gender in groups.

Confounder variables	Cases (n=21)	Controls (n=31)	OR with 95% CI
Male			
scores ≥ 18	2	3	0.17
scores< 18	8	2	0.01<OR<2.88
Female			
scores ≥ 18	1	9	0.19
scores< 18	10	17	0.01<OR<1.9
Age ≥ 60			
scores ≥ 18	3	9	**0.17**
scores< 18	16	8	**0.02<OR<0.9**
Age<60			
scores ≥ 18	1	2	6.00
scores< 18	1	12	0.05<OR<508.9
Comorbidities present			
scores ≥ 18	2	6	0.27
scores< 18	15	12	0.03<OR<1.93

There were no statistically significant differences in the groups of cases and controls with regard to gender. The only statistically significant result detected was related to the age of patients. For the group of patients aged 60 and over, the statistically significant protective effect against risk of stroke was found in patients with higher HCM scores, e.g. in the "better" managed patients. This indicates a synergistic interaction between age of hypertensive patients and "fair" management. To perform more complex analysis between different variables, for example, between age, gender and HCM, a logistic regression technique is required due to small sample size.

Table 7. HCM scores by categories adjusted for the age in stroke and non-stroke groups.

Categories	Age ≥ 60 (n=36)			Age < 60 (n=16)		
	Cases (n=19)	Controls (n=17)	OR with 95% CI	Cases (n=2)	Controls (n=14)	OR with 95% CI
Laboratory tests (at least 2)	10	11	0.13 0.13<OR<2.82	1	9	0.56 0.01<OR<26.5
Referrals (at least 2)	3	6	0.34 0.05<OR<2.1	0	4	0.00 0.00<OR<26.5
No advise given on non-pharmacological treatment	17	9	**7.56** **1.10<OR<82.7**	1	9	0.56 0.01<OR<26.5
No treatment at initial visit	10	3	5.19 0.93<OR<55.4	1	3	3.67 0.00<OR<2.76
at last visit	12	3	**8.00** **1.4<OR<55.4**	0	1	0.00 0.00<OR<2.76
Follow up visits ≥ 2 in first year	13	12	0.9 0.17<OR<4.67	1	9	0.56 0.01<OR<26.5

After a stratification by age, statistically significant differences between elderly in stroke and non-stroke groups were detected with regard to the absence of pharmacological treatment at last visit(8.00; 1.4<OR<55.4). The odds ratio of developing a stroke was also 7.5 times higher in the aged 60 and over compare to younger patients for whom no advise on non-pharmacological treatment was given.

Common patterns of HCM revealed in the aggregate group (n=52) of cases and controls are as following:

Table 8. Distribution of recorded process of HCM by different categories.

Category	Information recorded (% of charts)
Medical history: all items	55
complaints only	25
CV risk factors:	
not specified	53
smoking	20
overweight	0
lifestyle	6
alcohol use	13
Physical exam:	
heart exam	98
pulse exam	68
lung exam	98
Laboratory tests:	
blood test	58
urine test	58
total cholesterol[6]	8
Referrals:	
EKG	75
fundoscopy	26
neurological exam	34
Non-pharm. treatment:	
not specified	30
diet	32
exercise	10
weight control	0
alcohol intake limitation	15
smoking cessation	13
Follow up:	
visits in first year >1	43
<2	30
lost to follow	27
follow up visit date recorded	15

In general, higher scores were obtained in such categories of HCM as physical exam, laboratory tests and referrals. A limited information on medical history (complaints only) were found in one of four reviewed charts. No advice about non-pharmacological treatment of hypertension was recorded in the majority of

[6] The test is not always available.

the charts; the records of advice given[7] on smoking cessation, exercising, limitation of alcohol intake were rare findings during the review. No records of advice given on weight control was found.

Pharmacological treatment of hypertension: as it was described in the methodology of the study, the category of pharmacological treatment was not scored because it is difficult to evaluate an appropriateness of prescription of different classes of medicines. Nevertheless, the treatment preferences among primary health providers in Yerevan policlinic needs to be considered.

Table 9. Hypertension treatment preferences among district physicians in one of the policlinics in Yerevan.[8]

Type of medicines[9]	Initial visit	Last visit	OR with 95% CI
First choice medicines[10]	7 (13.4%)	9 (17.0%)	0.74 0.22<OR<2.4
Second choice[11] medicines	15 (28. 8%)	14 (36.4%)	1.1 0.4<OR<2.8
Other types of hypotensives	25 (48.4%)	27 (50.9%)	0.86 0.97<OR<1.9

As it is shown in the Table 9, about half of the prescribed antihypertensives does not belong to the classes recommended by JNC-5 guidelines. In the aggregate group of cases and controls, a period of time from first to last visit was 8.1 years (sd=4.5). Thus, over almost a decade, the treatment preferences have remained the same.

[7] The rates of smoking and alcohol use among patients may interfere the results.
[8] The figures may not sum up to 100% because not all the patients were treated.
[9] Recommended by Joint National Comittee on Detection, Evaluation, and Treatment of High Blood Pressure.
[10] Diuretics, β-blockers.
[11] CaCB, ACE-inhibitors, α- blockers.

Discussion

The main finding in this study of the effect of hypertension management on the hypertension -related adverse outcome was related to the age of patients. For the group of patients aged 60 and over, the statistically significant protective effect against risk of stroke was detected in patients with higher HCM scores. This indicates about 6 times higher OR of developing stroke for the patients of 60 years and over who were "poorly" managed as compare to those with "better" care. This association was statistically significant (0.17; $0.02<OR<0.9$). This is in agreement with the established benefits for the treatment of hypertension. The latest meta-analysis that included data from 3 trials in elderly patients demonstrated larger and more significant reduction in stroke and coronary events in elderly than was reported before in other studies[3,9,14]. The meta-analysis by Herrera C. R. from the Houston Medical School included 13 trials with aged and 12 trials with young and middle-aged patients also demonstrated the higher protective effect of the antihypertensive treatment for coronary events in older persons[23].

The protective effect against risk of stroke of the "better" management of hypertension in elderly demonstrated in the study in the Yerevan policlinic may be due to various reasons. Older patients may be more health-conscious and, therefore, have higher compliance with diagnostic and treatment procedures (since during the study period medical services were free of charge). Hypertension in elderly persons may be of different pathophysiological nature than in younger hypertensives and, therefore, a response to treatment procedures may differ, especially if the treatment was not adjusted for age.

The main finding of the study is a statistically significant protective effect against risk of stroke detected in patients with higher HCM scores. Nevertheless, not all categories of HCM have equally contributed to

the end-result of the study. As it was shown in Table 7, the OR of developing stroke was 7.5 times higher in the elderly patients for whom no advice on non-pharmacological treatment (1.65<OR<419) was given, and 8 times higher for whom no treatment (1.4<OR<55.4) was prescribed at last visit. On the contrary, there were no significant differences between stroke and non-stroke patients with regard to the diagnostic procedures, as laboratory tests and referrals, and follow-up procedures. Thus, the demonstrated effect against risk of stroke of "better" management of hypertension in the elderly patients is not due to higher utilization of the diagnostic procedures, but based on the categories of non-pharmacological and pharmacological treatment.

Although the absence of pharmacological treatment at initial visit was not statistically significant (10.0; 0.52<OR<3.88), it may be considered as clinically significant. Mean SBP in the group of elderly patients for whom no pharmacological treatment was prescribed at initial visit increased from 148.3 mmHg (sd=13.4) to 162.0 mmHg (sd=18.1) at last visit. At the same time, in the group of elderly who were prescribed medicines at initial visit, mean SBP decreased from 163.3 mmHg (sd=22.2) to 157.4 mmHg (sd=21.3). Thus, a pharmacological treatment was prescribed at first visit to the elderly patients with severe hypertension more often than to patients with mild hypertension (130-159 mmHg). Since the prevalence of high blood pressure increases with the age, an underestimation[12] of the importance of an early treatment may lead to the uncontrolled advancement of hypertension in the elderly patients.

Five classes of antihypertensive drugs are now recommended to treat hypertension. The most common approach is to begin treatment with a single drug. If control is inadequate, the dose is increased or other classes of drug are added. This approach, called stepped care, implies a treatment according to a precisely defined protocol [23].

The first step in the treatment should be non-pharmacological measures and lifestyle modification [9]. In about half of patients, no history on cardiovacular risk factors was taken (Table 8). No advice about non-pharmacological treatment of hypertension was recorded in the 70% of the charts; the records of advice given[13] on smoking cessation, exercising, limitation of alcohol intake were rare findings during the review. No records of advise given on weight control was found, which reflects an absence of a clinical evaluation of anthropologic data.

In the choice of initial therapy it is important to consider such factors as coexisting conditions, side-effects, presence of left ventricular hypertrophy (LVH) and target organ damage[10, 24]. The presence of the mentioned factors could be revealed through carefull diagnostic procedures. In the study, the diagnostic procedures as physical exam, laboratory tests and referrals, obtained the highest HCM scores (Table 8). Nevertheless, the high utilization of the diagnostic procedures did not result into the prescription of an appropriate antihypertensive therapy. As it was shown in the Table 9., about half of prescribed medicines does not belong to the classes of antihypertensive drugs recommended for a treatment of hypertension[3]. They represent such classes of medicines as rauvolfia, spasmolytics, sedatives or combination formulas. On the contrary, the first choice medicines were prescribed to only 17.0% and the second choice medicines to 26.4% of the hypertensive patients. Even taking into account the occasional necessity of individualising therapy to the specific patient rather than strictly following a stepped care approach, such figures reflects a deficiency in the clinical evaluation of a hypertensive case and a lack of adoption of stepped care approach. In total, 37 (71%) hypertensive patients in the

[12] There is a common misconception among district physicians that a mild increase of blood pressure in elderly is not a pathologic process, and, therefore, should not be actively treated.
[13] The rates of smoking and alcohol use among patients may interfere the results.

aggregate group of cases and controls[14] were considered as "poorly" managed since their HCM total scores were lower than 60% cutpoint.

The study has several limitations. The results are not widely generalisible because the study was conducted in only one of the 28 policlinics in Yerevan. The policlinic was chosen purposively, being the one of the top ranked policlinics in the city with strong managerial traditions and low turnover of personnel. Sample size in the study was limited to the number of all available cases (n=21). Postsampling calculations revealed that the power was only 25% to detect the observed differences of δ=0.16 in the frequency of "poor" management in two populations (80.9% and 64.5% in stroke and non-stroke patients accordingly) at 90% confidence level.

The other major limitation of the study is due to low validity of the data source, i.e. medical chart records. The validity of records may significantly vary for the different providers and settings. To assess validity of records, direct observations are needed.

The main source of bias in a case-control study is due to the selection of cases and controls. The study population were patients in community-based ambulatory health care settings. Therefore, patients who applied for any reason for care and had medical charts in the policlinic with a recorded high blood pressure, were subjects for the study. Identification of hypertensive patients who had developed stroke in the specified period of time, was done through multiple sources of data to minimize a selection bias. Cases of stroke (fatal and non-fatal) satisfying all eligibility criteria were included in the group of cases. Among total number of 21 cases, 16 were ascertained through more than one administrative data source. Controls were selected among the same population of patients in the policlinic who have a history of

[14] 16(80%) of cases and 16(53%) of controls.

hypertension and for whom a physician home visit was made in the same period of time when cases had developed stroke. Another possible option for selection of controls was to select them randomly from the lists of hypertensive patients available for each of 18 physicians in the policlinic. This option was rejected because the data were not updated and complete. Also, a misclassification bias would be a serious problem because the elderly hypertensive patients were often misdiagnosed with so-called "atherosclerosis".

Another source of bias could be the checklist for the assessing hypertension case management. The assessment of the categories of physical exam, laboratory tests and referrals was done only in relation to the initial visit. Such an approach was based on the assumption that the management at initial visit has a tremendous impact on the whole process of the management of a hypertensive patient. Although initial visits were made at the different points of time for each of the cases and controls, the analysis of data revealed that the mean duration of diagnosed hypertension and, therefore, the period of time from initial to last visit and the possibility for the exposure to HCM, were very similar in two groups (8.8 yrs in cases with sd=5.5 and 7.8 yrs in controls; sd=4.1). The other concern is about referrals for the specialized diagnostic procedures, such as EKG, fundoscopy and neurological exam. The assessment was done for the procedures that patients complied with. This is in fact a result of more complex relationship between a physician and a patient. Ideally, the management should be assessed for both referrals and completed exams. Otherwise, the patient non-compliance with diagnostic procedures may bias the results.

The following obstacles to implementation of the broader study were revealed during a trial to include more settings in the study. In some Yerevan policlinics, patient medical charts were distributed a few years ago to the patients to be kept at home. In reality, most records are lost. Because of unavailability of medical records, only patient interview based information was obtained in the one of the Yerevan

policlinic. This type of information could not provide us the necessary data to answer the research questions about hypertension case management by health care providers. Thus, with the charts not kept in the policlinics the continuity of care has been interrupted and medical charts as a source of documented care has lost its linking role between provider and patient. This presents obstacles to future studies that rely on patient records as a source of data. Moreover, after the study was designed and ready for the implementation, access to care was affected by the introduction of fees for medical services. In this situation, the efficiency of care should be a primary goal in the delivery of ambulatory health care. Suprisingly, there are no quality of care officers in the city health care department and the Ministry of Health. The ongoing reforms on structural changes of health care in Armenia should be aimed at improvement of quality of care and maintaining equitable access, especially for elderly patients. The system of monitoring and evaluation of quality of care should be developed as a part of the current movement towards health care reform.

Recommendations

Considering the results of the study about the preventive effect against stroke of the "better" management among elderly hypertensive patients aged 60 and over, the following is recommended:

i) To develop and implement a hypertension control program for elderly hypertensive persons. Such a program may consist of several parts: training of medical staff, patient education and empowerment, provision of medicines and evaluation of the program's effectiveness.

ii) Postgraduate training curricula for physicians and licensing requirements should be enhanced by including the standard condition-specific protocols for case management. The necessity of non-pharmacological treatment and lifelong pharmacological treatment with the internationally recognised medications should be emphasized.

iii) To establish a system for quality of care continuing improvement at local and national levels. The system should be based not only on record audit, but also on patient interview and direct observation.

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Appendix: Record Review Checklist for Hypertension Case Management Assessment

Record review #:	Patient's name:
Date of record review:	Address:
Additional information:	Phone

No.	Sociodemographic information	Code
1.	Gender	M [1] F [2]
2.	Date of birth	day/month/year / /
3.	Occupation[15]	Retired[1] Blue-c[2] White-c[3] Unemp[4] Other[5]
4.	Type of medical chart[16]	Usual [1] Dispanser [2]

No.	Initial visit		Code	Score	Notes
5.	Date of first time recorded high blood pressure		day/month/year / /	None	
6.	SBP, mmHg	130-159	Yes [1] No [2]	None	
		160-179	Yes [1] No [2]		
		180>	Yes [1] No [2]		
7.	DBP, mmHg	80-99	Yes [1] No [2]	None	
		100-109	Yes [1] No [2]		
		110-140	Yes [1] No [2]		
8.	Type of hypertension according to the diagnosis		Essential [1] Atherosclerotic [2] Renal [3] Other [4]	None	

No.	Medical history taken at initial visit	Code	Score	Notes
9.	Complaints	Yes [1] No [2]	1 point	
10.	History of vitae	Yes [1] No [2]	1 point	
11.	History of disease	Yes [1] No [2]	1 point	
12.	Family history recorded on any of the following: hypertension, diabetes, stroke, ischemic heart disease.	Yes [1] No [2]	1 point	

No.	Risk factors information at initial visit	Code	Score	Notes
13.	Cardiovascular risk factors or their absence recorded (non-specified)	Yes [1] No [2]	1 point	
14.	Currently smoking	Yes [1] No [2]	1 point	
15.	Overweight	Yes [1] No [2]	1 point	
16.	Sedentary lifestyle	Yes [1] No [2]	1 point	
17.	Alcohol use	Yes [1] No [2]	1 point	

[15] The data on occupational status were not updated and, therefore, not used in the analysis.

[16] There are two types of medical charts in Yerevan policlinics: usual and charts for the patients who need regular follow up (dispanser).

No.	Physical exam at initial visit	Code	Score	Notes
18.	Heart exam	Yes [1] No [2]	1 point	
19.	Pulse measurement	Yes [1] No [2]	1 point	
20.	Lung exam	Yes [1] No [2]	1 point	

No.	Laboratory tests in a first year	Code	Score	Notes
21.	Total cholesterol	Yes [1] No [2]	1 point	
22.	Blood test	Yes [1] No [2]	1 point	
23.	Urine test	Yes [1] No [2]	1 point	

No.	Referrals made in a first year	Code	Score	Notes
24.	EKG	Yes [1] No [2]	1 point	
25.	Fundoscopy	Yes [1] No [2]	1 point	
26.	Neurological exam	Yes [1] No [2]	1 point	

No.	Non-pharm. treatment at initial visit	Code	Score	Notes
27.	General recommendations (non-specified)	Yes [1] No [2]	1 point	
28.	Diet	Yes [1] No [2]	1 point	
29.	Physical exercise	Yes [1] No [2]	1 point	
30.	Weight control	Yes [1] No [2]	1 point	
31.	Alcohol intake limitation	Yes [1] No [2]	1 point	
32.	Smoking cessation	Yes [1] No [2]	1 point	

No.	Pharmacological treatment at initial visit	Code	Score	Notes
33.	None	Yes [1] No [2]	None	
34.	Diuretic	Yes [1] No [2]	None	
35.	CaCB	Yes [1] No [2]	None	
36.	β-blocker	Yes [1] No [2]	None	
37.	ACE-inhibitor	Yes [1] No [2]	None	
38.	α-blocker	Yes [1] No [2]	None	
39.	α-β blocker	Yes [1] No [2]	None	
40.	Other hypotensives	Yes [1] No [2]	None	

No.	Pharmacological treatment at last visit	Code	Score	Notes
41.	None	Yes [1] No [2]	None	
42	Diuretic	Yes [1] No [2]	None	
43.	CaCB	Yes [1] No [2]	None	
44.	β-blocker	Yes [1] No [2]	None	
45.	ACE-inhibitor	Yes [1] No [2]	None	
46.	α-blocker	Yes [1] No [2]	None	
47.	α-β blocker	Yes [1] No [2]	None	
48.	Other hypotensives	Yes [1] No [2]	None	

No.	Follow up after initial visit	Code	Score	Notes
49.	Number of visits to physician in the first year (**n**)	Yes [1] No [2]	1 point	if **n** 3 **2**
50.	Number of BP measurements in the first year (**m**)	Yes [1] No [2]	1 point	if **m≥n**
51.	Follow-up visit date recorded	Yes [1] No [2]	1 point	

52.	Lost to follow up after the first year	Yes [1] No [2]	1 point	if No[2]

No.	Last visit		Code	Score	Notes
53.	Date of diagnosis of stroke		/ / day/month/year	None	Omit for non-stroke patients
54.	Date of the last visit		/ / day/month/year	None	For stroke patients - prior to stroke
55.	Medication used at time of the last visit recorded		Yes [1] No [2]	1 point	For stroke patients - prior to stroke
56.	BP measurement at the last visit		Yes [1] No [2]	1 point	For stroke patients - prior to stroke
57.	SBP, mmHg	130-159 160-179 180	Yes [1] No [2] Yes [1] No [2] Yes [1] No [2]	None	
58.	DBP, mmHg	80-99 100-109 110-140	Yes [1] No [2] Yes [1] No [2] Yes [1] No [2]	None	

No.	Comorbidities	Code	Score	Notes
59.	Diabetes	Yes [1] No [2]	None	
60.	Ischemic heart disease	Yes [1] No [2]	None	
61.	Congestive heart disease	Yes [1] No [2]	None	
62.	Chronic obstructive pulmonary disease	Yes [1] No [2]	None	
63.	Asthma	Yes [1] No [2]	None	
64.	Prostatic hypertrophy	Yes [1] No [2]	None	
65	Other	Yes [1] No [2]	None	