

## Factors of non-compliance with the therapeutic regimen among hypertensive men and women: A case-control study to investigate risk factors of stroke

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**Abstract.** To identify potential risk factors among the therapeutic regimen and life style which may increase the risk for stroke, a pair matched case-control study was conducted in Gaza Strip among 112 patients, who had been hospitalized for acute stroke and history of hypertension, and 224 controls with history of hypertension. Conditional logistic regression models show significant associations between stroke and medication not taking as prescribed (OR = 6.07; 95% CI: 1.53, 24.07), using excessive salt at meals (OR = 4.51; 95% CI: 2.05, 9.90), eating diet high in fat (OR = 4.67; 95% CI: 2.09, 10.40), and high level of stress (OR = 2.77; 95% CI: 1.43, 5.38). No significant association between smoking and the development of stroke (OR = 2.12; 95% CI: 0.82, 5.51)

was found. Regular physical exercise was a protective factor (OR = 0.26; 95% CI: 0.12, 0.57). Using excessive salt at meals was a significant risk factor (OR = 16.61; 95% CI: 4.40, 62.80) in people having low level of stress, whereas it was not significant in people having high level of stress. (OR = 1.76; 95% CI: 0.58, 5.33). Smoking in combination with low level of stress was a significant risk factor for stroke (OR = 9.88; 95% CI: 2.52, 38.78), but a non-significant protective factor in combination with high level of stress (OR = 0.52; 95% CI: 0.14, 1.99). An increase in compliance with the pharmacological and non-pharmacological therapeutic regimen might be a key to a reduction of stroke incidence and prevalence among hypertensive patients.

**Key words:** Compliance, Hypertension, Prevention, Risk factors, Stroke

### Background

Hypertension is worldwide a public health problem affecting about 20% of the adult population, responsible for over 70% of stroke in women and 40% in men and the single most important potent risk factor for stroke [1–7]. It is one of the main causes which contribute to disability, health care costs, and stroke mortality [8, 9]. Stroke, a possible consequence of hypertension often leads to death and disability [4, 10–12]. The American Heart Association estimates that stroke occurs in 500,000 Americans each year [13–15]. In developing countries, stroke remains as one of the major public health problems [12].

In Gaza Strip and West Bank cerebrovascular diseases are the second leading cause of death of the total cardiovascular disease mortality (35% in Gaza Strip, and 27.5% in West Bank). The mortality rate among people of 60 years of age and over is highest in patients with cerebrovascular disease (15.2%), in comparison to hypertension (11.3%), malignant neoplasm (9.1%), diabetes mellitus (5.3%), and renal failure (3.2%) [16].

Non-compliance to the pharmaceutical and non-pharmaceutical therapeutic regimen (usage of

anti-hypertensive medication, dietary restrictions of sodium and fat, weight reduction, exercise program) is associated with complications of hypertension, such as stroke [15, 17–19]. Surveys indicate that therapeutic compliance to non-pharmacological advice and even to drug prescriptions is far from being excellent. Non-compliance limits the efficacy of the prevention strategies and contributes to a markedly increase of associated cardiovascular complications [20]. Further potential risk factors for stroke are obesity, high cholesterol, smoking, and alcohol consumption [21]. In addition to hypertension these risk factors may increase the risk of stroke [17–19, 22]. Physical activity is a significant protective factor in men, but not in women [23].

A WHO expert committee [1] reported that the prevention of stroke by anti-hypertensive therapy has been successful, but more research is required to evaluate the effectiveness of anti-hypertensive therapy and life style modification in preventing stroke and recurrent stroke, especially the impact of anti-hypertensive treatment in secondary prevention of stroke [1, 6].

A case-control study was carried out in Gaza Strip to investigate whether a significant association exists

between non-compliance with the therapeutic regimen (e.g. usage of anti-hypertensive medication, dietary restrictions in sodium and fat, implementation of weight reduction and exercise program, regular follow-up health care, and smoking) and the development of stroke among hypertensive patients.

### Materials and methods

Cases and controls were recruited from the same geographical area in Gaza Strip [24, 25]. Three main hospitals in Gaza Strip (Shefa, Nasser, and European hospital) and the geographically and administratively related primary health care clinics were pinpointed for the selection of the study population. Each selected primary health care clinic was associated with one of the three hospitals in relation to diagnostic and treatment as well as follow-up procedures. The population under study consists of patients aged between 35 and 69 years.

#### *Selection of cases and controls*

All available discharge data of patients from the selected hospitals were screened for cases. Patients who had been hospitalized for acute stroke and history of hypertension between 1st January and 31st December 2001 were defined as cases ( $n = 180$ ). According to exclusion criteria, 68 (38%) cases were excluded. In total 112 (62%) cases were ultimately selected from the registers. The diagnosis of stroke was confirmed by a physician and a head CT scan was performed. Stroke was defined as 'a sudden loss of brain function resulting from disruption of the blood supply to a part of the brain' [21].

Controls were defined as having hypertension only, without history of stroke prior to interview. Controls may have developed stroke later on after the study period. The occurrence of potential later development of stroke in controls after the interview was studied for the period of the study by telephone follow-up interview and clinic visits. During the period of the study no one of the controls developed stroke. These patients with a diagnosis of hypertension received health care follow-up because of anti-hypertensive medication in eight governmental primary health care clinics. Controls were selected from the same primary health care clinics where cases used to receive follow-up appointments for hypertension on primary health care level before hospital admission due to the development of stroke.

#### *Inclusion/exclusion criteria*

Both, cases and controls had received anti-hypertensive pharmaceutical treatment for at least one year before enrollment into the study. A physician made a diagnosis of stroke and/or hypertension. Hypertension

was defined when the threshold levels of 140 mm Hg systolic and 90 mm Hg diastolic were reached at three different independent measurements within one week, repeated twice over a 2 months period prior to the diagnosis of hypertension. Further grading into mild, moderate, severe hypertension was not made. A computed tomography head scan had been carried out in patients with stroke. Both groups were selected only, if a history of other physical diseases (diabetes, myocardial infarction, atrial fibrillation, pulmonary oedema, asthma) was excluded. Sixty-eight (38%) out of 180 selected cases were excluded from the study: 19 (28%) died after first stroke; eighteen (26%) had a second stroke; seven subjects (10%) were over 69-years-old; 10 (15%) participated in the pilot study; seven (10%) patients had no computer tomography head scan; four (6%) refused to participate in the study; three (4%) patients started their therapeutic regimen less than one year. Patients participating in the pilot study and test-retest study were excluded to reduce response bias.

#### *Study design*

A one to two matched case-control study was carried out. The case group consists of 112 subjects with stroke and history of hypertension only, and the control group consists of 224 subjects with hypertension only. Cases and controls were matched by age, sex, starting point of therapeutic regimen for both pharmacological and non-pharmacological treatment, time of hypertension, enrollment location of hospital related health care clinics and calendar time. For each case two identical controls were recruited to detect small differences between the two groups [24] and to compensate potential loss of controls. To test feasibility, validity and reliability of the instrument a small-scale study was carried out by using a small sample consisting of 10 cases of stroke with history of hypertension (five males and five females), and 20 patients with hypertension only as a control group. Minor adjustment of the questionnaire was done. Probands of the pilot study were excluded from study population.

#### *Questionnaire*

The questionnaire has been developed from two sources. The first part, which deals with personnel, (age, sex, address, marital status, number of children), medical, and socio-economic status, was developed by ourselves, and the second part, which deals with therapeutic regimen (anti-hypertensive medications, dietary restriction of sodium and fat, weight reduction, exercise program, follow-up health care) has been adopted from a medical-surgical book [21]. Compliance with anti-hypertensive medication was measured with three single categorical ('yes' vs. 'no') items [(1) 'medication taking as prescribed'; (2)