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Original article

mHEALTH APPLICATION AS A TOOL TO ASSIST FAMILY DOCTORS IN THE MANAGEMENT OF HYPERTENSION

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Abstract

Introduction: Hypertension is a leading cause of overall morbidity and mortality worldwide. The management of uncomplicated hypertension remains at the primary health care level, which requires good work organization in primary care clinics in order to enable patient-centered care according to evidence-based medicine.

Aim: The aim of this study was to determine the impact of using a mHealth application in work organizing of primary care clinics in managing patients with newly diagnosed hypertension in RN Macedonia.

Material and methods: A prospective randomized controlled multicenter study with 12-month follow-up of newly diagnosed patients with hypertension was performed. The intervention group received standard care + mHealth application, while the control group received only standard care. The mHealth application enabled transmission of measured blood pressure values in real time and two-way doctor-patient communication via SMS messages. The study monitored the number, reasons and justification of additional visits in the primary care clinic.

Results: From 192 participants included, 75(39.06%) had an additional visit - 23(24.21%) in the intervention and 52(53.61%) in the control group (p=0.0001). In terms of the number of additional visits per patient, only 1 in the intervention *versus* 17 in the control group had 3 emergency examinations (p=0.004). The most common reason for examination was blood pressure measurement in 15(7.81%) patients. No adverse events were recorded in either group.

Conclusion: The mHealth application with two-way patient-doctor communication represents an additional intervention to standard care that can reduce the need for "face-to-face"visits with a family doctor and provides an opportunity for better organization of work in family doctor outpatient clinics.

Keywords: mHealth application, hypertension, family doctor, face-to-face visit

Introduction

Arterial hypertension (HTA) is a global public health problem and a leading cause of overall morbidity and mortality worldwide [1,2]. According to the WHO report, in North Macedonia in 2019, the prevalence of diagnosed patients with HTA was 45%, of which 49% were male, and

41% were female patients[3]. Management of patients with uncomplicated HTA according to global recommendations remains at the level of primary health care. Underdiagnosed, undertreated and/or poorly managed HTA is directly associated with higher cardiovascular risk and the occurrence of cardiovascular diseases (cerebrovascular stroke, myocardial infarction[4], heart failure, blindness, sexual dysfunction and chronic renal failure)[5,6]. Target organ damage is a cause of early morbidity, disability and mortality in the working population. According to the Global Burden of Disease, Injury and Risk Factors (GBD) study in 2019, arterial hypertension is the leading risk factor of level 2 at the global level, with 10.8 million (95% uncertainty interval [UI] 9.51-12.1) deaths (19.2% [16.9-21.3] of all deaths in 2019). On the other hand, data from a repeated study in GBD 2021 show that the number of deaths associated with HTA, despite the COVID 19 pandemic, is increasing and is still in the first place[7].

Hypertension is often not the only chronic non-communicable disease a patient has. More commonly, there is the simultaneous presence of one or more other diseases or conditions, such as dyslipidemia, diabetes mellitus, arthrosis, etc., where due to additional burden, subclinical complications of hypertension occur more quickly, indicating a high risk for subsequent clinical events[8].

The treatment of hypertension is based on two basic interventions, non-pharmacological and pharmacological therapy. The primary care physician, during the diagnostic protocol and monitoring of patients with HTA, needs to provide an individualized treatment as a combination of non-pharmacological and pharmacological treatment and structured examinations in order to achieve targeted blood pressure (BP) values and reduce cardiovascular (CV) risk. Despite following the recommendations of cardiology societies for appropriate management of patients with HTA, according to WHO, only 21% of diagnosed patients reach target BP values worldwide[9]. Reports of good BP control in the Republic of N. Macedonia follow global trends with 23% of HTA patients with well-controlled BP values, which indicates poor hypertension control in our country[3].

Although the standard of care defined by recognized cardiology societies[10] is imperative in the management of this disease, the implementation of the recommendations depends greatly on the regions of the countries and their economic development on one hand, but also on the health professionals and patients on the other. A large number of discrepancies between the recommendations for the management of HTA and standard of care have been defined and they are the result of various obstacles to implementation from 3 parties: patients, health professionals and health systems[11-13]. From doctors' perspective, the obstacles consist of a lack of knowledge of guidelines and appropriate blood pressure goals, a large number of patients, and a lack of time to address hypertension given the increasing number of other patient needs[14]. All this leads to the appearance of clinical inertia in starting and/or deficits in intensifying the dose of drugs to achieve targeted blood pressure values[15]. By health institutions at the PHC level, among other things, barriers in the management of HTA have been recorded in the organization of work, which leads to: lack of time or resources to provide patients with appropriate education and standardized care, the need for systems to identify and monitor patients with poorly controlled blood pressure.

Patients with uncontrolled or optimally controlled hypertension also frequently visit their primary care clinics for BP measurements and medication refills, which places a huge burden on the PHC health system. For better resource allocation in healthcare, telemedicine systems have the potential to reduce the number of doctor consultations by automatically confirming optimal BP control (BP values measured at home) and medication refills. Well-implemented telemedicine

systems can help health systems cope with higher patient volumes and facilitate better resource allocation[16].

The aim of this study was to determine the impact of using an mHealth application in organizing the work of primary care clinics in managing patients with newly diagnosed arterial hypertension in the Republic of N. Macedonia.

Material and methods

The study was designed as a prospective randomized controlled multicenter study with 12-month follow-up of newly diagnosed patients with HTA (2023/2024), followed by 19 family physicians on the territory of the Republic of N. Macedonia. An appropriate sample of family physicians and participants was determined for the study.

The sample of family physicians was determined by meeting the following inclusion criteria: ≥500 patients aged 35-70 years, owning ≥1 computer (with minimum Windows 7), stable internet connection, desire and signed consent to participate in the study. Exclusion criteria: doctors who replace each other (which makes it impossible to follow the protocol and challenges the protection of personal data), lack of readiness and desire to participate in the study.

The study sample was required to meet the following inclusion criteria: newly diagnosed patients with HTA, aged 35-70 years, possessing a smartphone, having a standardized semi-automatic or automatic sphygmomanometer, willingness and desire to participate in the study. Exclusion criteria: comorbidities (heart failure, chronic renal failure, hepatic failure, malignant diseases, secondary hypertension), pregnancy, cognitive diseases or problems with understanding instructions and patients who did not sign an informed consent. The included patients were divided into two groups (intervention/control) using a simple random selection method. Patients in the intervention group (IG) received standard care and mHealth application, while those in the control group (CG) received only standard care. According to the protocol, both groups had structured control visits in the doctor's office at 1, 3, 6 and 12 months from inclusion in the study.

According to the set inclusion and exclusion criteria for family doctors, an unmasked study was conducted. Randomization of outpatient clinics was performed using the simple random selection method by region in a 1:1 ratio, assigning outpatient clinics either an intervention group or a control group across the 8 regions in the Republic of N Macedonia. Patients who met the criteria were assigned to the IG or CG, based on the distribution by group of the family doctor to whom they belonged.

Intervention description

mHealth application was created with the support of the software company Angor AG from Struga, Republic of N. Macedonia and consisted of 2 parts: a mobile application for patients and a program with a database for the family doctors involved in the study.

The mobile application consisted of 3 parts: a part where patients entered measured BP and pulse values; a part intended for two-way exchange of messages between the doctor and the patient in 2 forms (an info message, and a message with an attached document); and an informational part for the patient with access to a video link on the technique of correct BP measurement with a document on a dietary regimen and appropriate physical activity. The mobile application was installed on the mobile smartphone of the patient included in the intervention group and it was activated by the doctor with the patient's mobile phone number.

The program with the database for doctors consisted of 3 parts: a part with patient data, a part for monitoring the measured values for BP and pulse that the patient entered into his

application, and a part intended for two-way exchange of SMS messages between the doctor and the patient in 3 forms: an info message, a message with an attached document and a warning message (for high TA, change of therapy, or calling a patient to the outpatient clinic). Entry into the program was possible only with a special code and password provided to each doctor in order to protect patient data.

Participants in the intervention group received education on day zero on how to download and activate the application on the their mobile phones and were trained to use it for entering BP measurements taken at home. Patients also received a short leaflet on the frequency of entering measured BP values (every day - morning and afternoon for the first 2 weeks, then 5 days a week - morning and afternoon for up to 1 month, then 3 days a week - morning and afternoon - for the next 3 months, then 2 days a week - morning and afternoon until 12 months after entering the study).

The intervention in the intervention group lasted 12 months, i.e. throughout the entire study.

The outcome was the number of additional visits in the primary care clinics outside of the planned controls in both groups and adverse events related to BP in the intervention group.

Monitoring of emergency examinations

The study covered the number, reasons and justification of additional examinations at the primary care clinic. For this purpose, an "Additional Visit Examination " form was prepared and filled out by the primary care physician for each patient included in the study who needed an additional visit beyond the planned controls at 1, 3, 6 and 12 months. The form included the following parameters: reason for the additional examination, clinical examination (heart and lung auscultation, presence of peripheral edema, values for measured systolic and diastolic blood pressure, pulse) and interventions given by the the family doctor (changes in pharmacological therapy, changes in non-pharmacological therapy, referrals to a specialist at the secondary or tertiary level of health care and referral for a diagnostic procedure - abdominal ultrasound, chest X-ray, carotid Doppler). BP measurement during the planned controls according to the protocol and additional visits was performed with a validated Omron M2 digital manometer device for measuring upper arm blood pressure in both groups.

Statistical analysis

Data obtained in the study were processed with the SPSS software package, version 2 6 .0 for Windows. The analysis of qualitative series was done by determining the coefficient of relationships, proportions and rates, and they were displayed as absolute and relative numbers. The numerical (quantitative) series were analyzed with the measures of central tendency (average, median, minimum values, maximum values, interactive ranks), as well as with measures of dispersion (standard deviation, and standard error). Pearson Chi square test, Fischer exact test and Fisher Feeman Halton exact test were used to determine the association between certain attributive dichotomous traits.

Results

According to the criteria, a total of 192 (100%) patients with HTA were included in the study, who were divided into two groups (interventional/control) using a simple random selection method. Patients in the IG received standard care + mHealth application, while those in the CG received only standard care. The study assessed the effect of using a mHealth application on the number of additional visits in the primary care clinic outside of planned controls in both groups

and adverse events related to BP in the intervention group. The number of additional visits and reported side effects were monitored over the 12 months of the study.

Regarding the gender distribution of 95 (100%) patients with IG , it indicated the presence of 46 (48.42%) men and 49 (51.58%) women. The average age of patients in IG was 49.53 ± 8.90 [95% CI (47.71–51.34)] years, with the age range of 35/70 years. Patients in the CG had a mean age of 48.43±7.30 [95% CI 46.96–49.90)] years, with the age range of 35/66 years.

Patients from each of the two groups, IG and CG, were analyzed regarding the additional visits performed, the reason for the visit, and the subsequent findings (Tables 1 and 2 and Figures 1, 2, 3 and 4).

Number of additional visits - A total of 75(39.06%) patients in the sample had an emergency examination: 23(24.21%) patients in the IG and 52 (53.61%) in the CG. The percentage difference between the representation of respondents with an emergency examination from the two groups was statistically significant (Difference test: 29.40% [(15.69-41.58) CI 95%]; p=0.0001) in addition to a significantly higher percentage representation of patients from the CG (Table 1 and Figure 1).

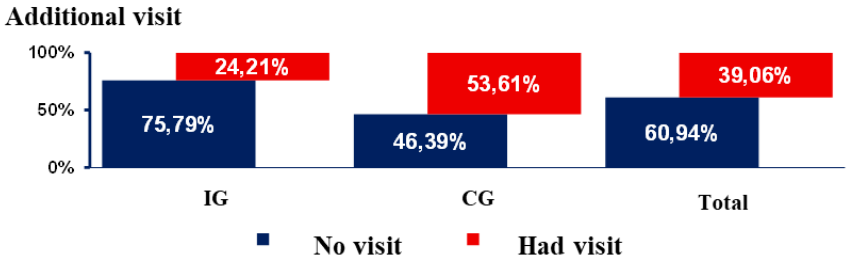

Fig. 1. Distribution of additional visits in the entire sample and by groups

Number of additional visits per patient - Of the 23 patients from the IG who required additional visits, 22 patients had 1 emergency examination (95.65%), and 1 patient required 3 emergency examinations within 12 months (4.35%). Of 52 patients from the CG with an additional examination, 22 patients had 1 additional visit (42.3%), 17 patients required 2 visits (32.7%), 10 patients required 3(19.23%), 2 patients 4(3.85%) and 1 patient 6 additional examinations (1.92%). The percentage difference between the number of visits per patient in the two groups was statistically significant (**Chi-square test** 15.35, df:4, **p** = 0.004) in favor of a significantly higher number of visits per patient in the CG**.**

Table 1. Number of additional visits per patient in both groups

Number of additional visits per patient	Intervention group N=23	Control group N=52
1	22(95.65%)	22(42.3%)
2	0	17(32.7%)
3	1(4.35%)	10(19.23%)
4	0	2(3.85%)
6	0	1(1.92%)

Reasons for additional visits -The most common reason for an additional visit was blood pressure measurement reported by 15(7.81%) of patients, followed by headache - not related to BP in 9 (4.69%), elevated blood pressure in 5(2.60%), chest pain in 3(1.56%) and 1(0.52%) patient who indicated a check-up as the reason, i.e. not feeling well (Figure 2).

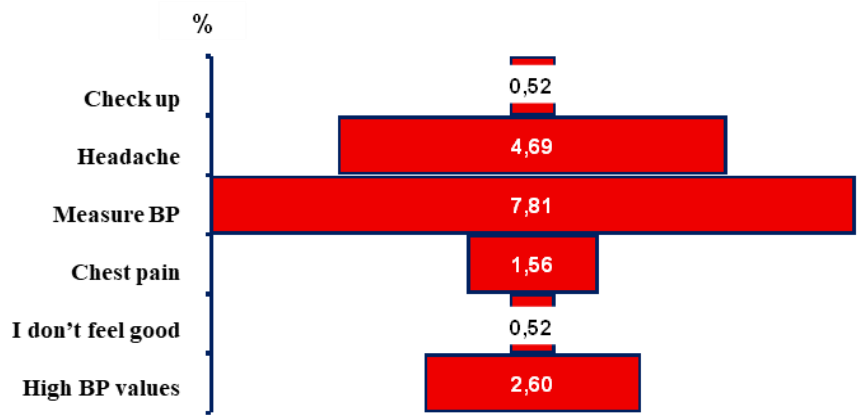

Fig. 2. Main reasons for emergency examination of patients in the entire sample

Parameters from the additional visits - Regarding heart auscultation - of the entire sample, heart auscultation was performed in all patients who requested additional visits - 75 (100%). In 73 (97.33%) of them, the heart auscultation finding was normal, and only in 2(2.67%) of the examined patients a pathological finding was determined. The findings of the emergency examination by groups indicated 23(100%) normal heart auscultation findings in the IG and 2(3.85%) pathological heart findings in the CG (Table 2).

Table 2. Clinical examination parameters during additional visits

Parameters			Groups IG	CG	Total
Emergency heart examination					
No examination		N (%)	72(75.79%)	45(46.39%)	117(60.94%)
There is an examination			23(24.21%)	52(53.61%)	75(39.06%)
Finding†	Edited	N (%)	23(100%)	50(96.15%)	73(97.33%)
	Pathological		0(0%)	2(3.85%)	2(2.67%)
Emergency lung examination					
No examination		N (%)	72(75.79%)	45(46.39%)	117(60.94%)
There is an examination			23(24.21%)	52(53.61%)	75(39.06%)
Finding†	Edited		23(100%)	52(100%)	75(100%)
	Pathological		0(0%)	0(0%)	0(0%)
Emergency examination of peripheral edema					
No examination		N (%)	72(75.79%)	45(46.39%)	117(60.94%)
There is an examination			23(24.21%)	52(53.61)	75(39.06%)
Finding†	Edited		23(100%)	52(100%)	75(100%)
	Pathological		0(0%)	0(0%)	0(0%)
Extraordinary review of the SBP					
No examination		N (%)	72(75.79%)	45(46.39%)	117(60.94%)
There is an examination			23(24.21%)	52(53.61)	75(39.06%)
Finding	Mean ± SD		138.17±12.97	147.08±10.59	144.34 ±12.02
	Median IQR		140(130-150)	149(139-155)	148(135-152)
Extraordinary review of the DBP					
No examination		N (%)	72(75.79%)	45(46.39%)	117(60.94%)
There is an examination			23(24.21%)	52(53.61)	75(39.06%)
Finding	Mean ± SD		89.17±10.76	90.54±8.71	90.12 ±9.33
	Median IQR		90(80-100)	90(82-98)	90(80-100)

IG=standard care & mHealth app.; CG=standard care, † Calculations are based on the number of emergency visits/groups

Regarding an emergency lung examination and examination for the presence of peripheral edema in all patients from both groups, the findings for both parameters were normal (Table 2).

Blood pressure values measured during additional visits - Regarding an emergency finding for SBP - in all patients who requested an additional examination, SBP was measured. The average SBP in patients with additional visits from the entire sample was 144.34 ± 12.02 mmHg with 50% of patients with SBP ≤148 mmHg and 25% with SBP >152 mmHg. In the IG or CG during the examination, the average SBP was 138.17 ± 12.97 mmHg *vs.* 147.08±10.59 mmHg, and in 50% of patients in the IG or CG it was consistently ≤140 mmHg *vs.* ≤149 mmHg. Individually, in 25% of patients in the IG or CG, the SBP was >150 *vs.* >155 mmHg. A significant difference was found between the two groups (IG/CG) in terms of the height of the SBP at the additional examination in addition to significantly higher values in the CG for Mann-Whitney U Test: Z=(-2.666; p=0.0077 (Table 2 and Figure 3).

Regarding an additional finding for DBP – DBP measurement was performed in all patients who requested an additional visit. The average DBP in patients with additional visits from the entire sample was 90.12 ± 9.33 mmHg, with 50% of patients with SBP ≤90 mmHg and 25% with DBP > 100 mmHg. In IG or CG during the additional visits, the average DBP was 89.17 ± 10.76 mmHg *vs.* 90.54 ± 8.71 mmHg. In 50% of patients in IG or CG, DBP values were ≤90 mmHg. Additionally, DBP in 25% of patients from IG or CG was consistently >100 mmHg *vs.* >98 mmHg. There was no significant difference between the two groups (IG/CG) in terms of the height of the DBP at the additional visits for Mann-Whitney U Test: Z=(-0.344; p=0.7303 (Table 2 and Figure 3).

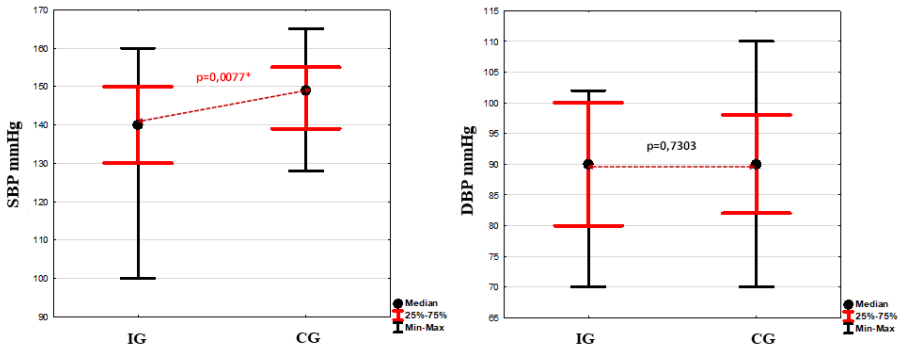

Fig. 3. Findings from the additional review for SBP and DBP by groups

According to the entered data for therapy change made – Within the framework of the additional visits of patients in the study, a change in therapy was made in a total of 72 (37.5%) patients out of 75, or specifically pharmacological therapy in 46 (63.89%) patients, non-pharmacological therapy in 18 (25%) patients, referral to a specialist in secondary - SHC / tertiary level of health care - THC in 13 (18.05%) patients and diagnostic method with abdominal ECHO in 2 patients (2.78%) (Figure 4).

During the study, no adverse events related to the study protocol were recorded in the either sample (IG/CG).

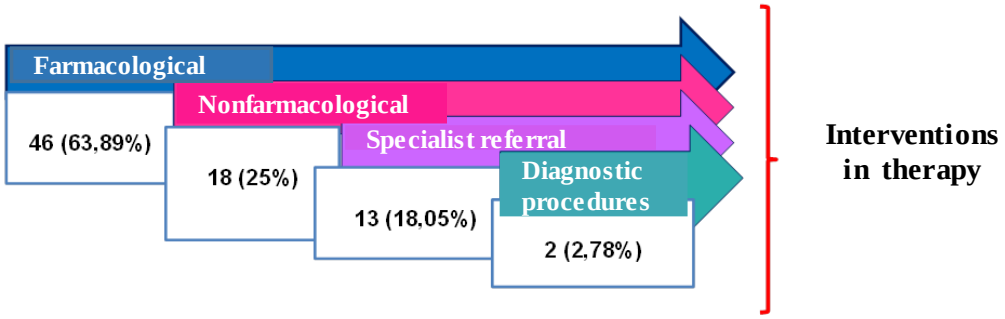

Fig. 4. Interventions in changing therapy by family doctors during additional visits

Discussion

The objectives of the study were to determine the impact of a dedicated mHealth application on a mobile smartphone + standard care on reducing the number of additional visits to the primary care clinic outside of planned controls in both groups over a 12-month period and adverse events related to BP in the intervention group. The introduction of the intervention is expected to reduce the need for visits to a family doctor with safe monitoring of patients with HTA remotely, which allows for proper use of health resources and better organization of work in primary care clinics. The study confirmed that the mHealth application reduced the need for additional examinations by a primary care doctor, i.e. <25% of the intervention group and >53% of the control group needed an additional face-to-face visit. At the same time, a decrease in the need for an additional visit per patient was also noted. In the intervention group, it was noted that only 1 additional visit was most often required, i.e. only 1 patient needed 3 additional examinations. In the control group, a higher frequency of additional visits was noted, where 1/5 of the patients required 3 and 1 patient even 6 additional examinations. This confirms the impact of the mHealth application on reducing additional visits in primary care clinics and saving human and financial resources and unjustified visits. Of the most commonly recorded reasons for additional visits, 1/7 of patients come to the clinic only to measure their blood pressure or have a headache unrelated to BP, which does not justify the reason for an unannounced examination in the clinic, while only 24% had a justified reason related to BP (chest pain, elevated blood pressure values and discomfort). During the study, no adverse event related to BP was recorded in any group, which indicates the safety of monitoring patients remotely with the mHealth application. The possibility of two-way communication via SMS from the application itself facilitates the patient's access to the doctor, but at the same time the doctor, observing the measured BP values in real time, gains direct insight into the control of the disease. This not only reduces the need for outpatient visits, but also enables seamless communication in disease management. The mHealth application certainly does not replace standard care, but rather complements it in order to improve health outcomes, reduce financial costs, and reduce the time it takes for the patient to arrive.

In the past decade, the role, safety, acceptability and feasibility of telemedicine systems in monitoring HTA have been intensively studied, but there is almost no research that has monitored the effect of mHealth applications or, more broadly, telemedicine in the organization of work in healthcare institutions.

A relevant study found in the literature is a pilot, multicenter randomized study by Wang *et al.*[17] in which the primary outcome was to determine the feasibility of using an mHealth application, while the secondary objective was to see the effect of the mobile application on the

number of outpatient visits. The study found that participants in the intervention group had fewer visits to general outpatient clinics (0.8 *vs*. 2, p<0.001), and no adverse events related to BP were observed in either group.

Although our study showed a clear reduction in the need for additional face-to- face visits, the number of examinations was also influenced by a number of other factors, such as a highly developed society, health culture, the organization of health systems, etc. A study conducted in Scotland confirmed a reduction in the number of examinations using a telemonitoring system, but not to the extent that it relieved the busy schedule of primary care physicians[18].

Conducting new research that will monitor the impact of mHealth applications on the organization of the work of healthcare professionals who are directly involved in managing patients with HTA is of exceptional importance, in order to confirm its positive effect on good BP control and the reduced number of additional face-to-face visits in outpatient clinics.

Conclusion

The mHealth application with two-way patient-physician communication is an additional intervention to standard care that can reduce the need for follow-up examinations with a family doctor. The use of the mHealth application allows for safe monitoring of patients with hypertension remotely and provides an opportunity for better organization of work in family doctor outpatient clinics.

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Conflict of interest statement. None declared.

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