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Management of arterial hypertension: Transfer from clinical guidelines into daily practice – Results of a survey in German practitioners offices

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Abstract:

INTRODUCTION: The principal objective of clinical guidelines is to improve the quality of medical care. However, standardized evaluation of the adoption into daily practice is missing. The aim of our study was to investigate the implementation of guideline recommendations on the management of arterial hypertension (AH) in German general practitioner's (GPs) offices.

METHODS: A questionnaire focusing on the implementation of the German guidelines for the management of AH was developed and prospectively rolled out in 3.200 GPs and field-based specialists in internal medicine in Germany. Data were interpreted in an explorative way.

RESULTS: Data from 689 German physicians that participated in the survey were analyzed. Effectiveness of lifestyle changes in the management of AH was rated as very high or high in 36.6%. When lifestyle changes only will not normalize blood pressure (BP), medical treatment will be initiated after 2–6 months by majority of physicians. Decision for mono- or combination therapy was driven by BP and patient's risk profile. Choice for a specific antihypertensive substance was based on the recommendations of scientific guidelines in the majority of GPs.

CONCLUSIONS: Medication treatment algorithms recommended in 2015 by German guidelines are well accepted by GPs. Lifestyle changes are voted by only slightly more than one-third as a reasonable tool for the management of AH in the setting of the medical office. This might reflect a lack of certified medical education regarding this topic. Our study was not designed to register the time from publication of guidelines to practical implementation.

Keywords:

Arterial hypertension, clinical guidelines, daily practice, implementation

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Introduction

The majority of clinical practice guidelines (CPGs) are based on sophisticated methodologies that translate scientific evidence into clinical practice.^[1] Arterial hypertension (AH) guidelines provide up-to-date information and recommendations for AH management to health-care professionals.^[2] Guidelines for the management of AH have been issued by the European Society of

Cardiology (ESC) and the European Society of Hypertension (ESH). Quality criteria for the development of guidelines have been established by both societies in order to make all decisions transparent. All experts that are involved in the writing and reviewing process provided declaration of interest forms for all relationships that might be perceived as real or potential sources of conflicts of interest. The task of developing the guidelines also includes the creation of educational material and implementation program including condensed pocket

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guideline versions, summary slides, and booklets with essential messages for daily practice. The full-text version of the guidelines is freely available via the ESC and ESH websites and hosted on the European Heart Journal and Journal of Hypertension websites. The German association of hypertension (Deutsche Hochdruckliga e.V., DHL) has translated and implemented the ESC/ESH guidelines and provided a translation of the pocket guidelines on their webpage. Information of the major recommendations of the national guidelines has also been published in the national journal "Deutsches Ärzteblatt," which will be provided to every German physician on a weekly basis.^[3] German physicians were also encouraged to offer their patients a guideline with the major recommendations for daily use.^[3]

The ESH and ESC demand that surveys and registries are needed to verify "that real-life daily practice is in keeping with what is recommended in the guidelines, thus completing the loop between clinical research, writing of guidelines, disseminating them and implementing them into clinical practice."^[4] The objective of our study was to follow this call and investigate the implementation of AH guideline recommendations in German general practitioner's (GPs) offices.

Methods

This was a survey covering a questionnaire with 12 closed questions focusing on the implementation of the German guidelines for the management of AH with main focus on lifestyle changes and medical treatment that was developed by hypertensiologists, cardiologists, and specialists in the development of surveys. The 2013 ESC/ESH guidelines for the management of AH defined indications/contraindications for the use of antihypertensive classes. In addition, one question focused on a ranking for the use of angiotensin receptor antagonists (ACEI), angiotensin receptor blocker (ARB), β -receptor blocker (BB), calcium channel blocker (CCB), and diuretics (D) under special predefined medical conditions (age >65 years, age <65 years, high cardiovascular (CV) risk, metabolic syndrome, kidney failure, and lack of compliance). This questionnaire was validated with 281 German physicians with a content validity ratio of 0.71 and a content validity index of 0.90.

3,200 GPs and field-based specialists in internal medicine in the whole German federal territory were prospectively asked by employees of APONTIS PHARMA, Monheim, Germany, for participation in the study. In case of participation, the paper-based questionnaire was answered and sent in an anonymized envelope to an independent institute (uzbonn) for data entry and analysis. According to the predefined investigation plan, data were summarized using basic descriptive methods and interpreted in

an explorative way. The descriptive analysis included frequency distributions, which were presented in histograms and diagrams, as well as some analyzes concerning the conditional filter function of some questions.

Results

Six hundred and ninety-eight German physicians participated in the survey, 689 were suitable for full questionnaire analysis (73.9% GPs, 26.1% specialists in internal medicine, thereof 1.7% hypertensiologists) and 654 gave information on gender (39.6% female). Location of participants by area of regional board of panel doctors (Kassenärztliche Vereinigung, KV) is given in Table 1 [Table 1].

About 20.2% treat <1000 patients (specialists 21.5%, GPs 19.8%), 44.9% treat 1000–1499 (specialists 41.8%, GPs 46.2%), 18.9% treat 1500–1999 patients (specialists 14.7%, GPs 20.4%), and 16.0% treat more than 2000 patients suffering from hypertension (specialists 22.0%, i.e., significantly more than GPs with 13.5%).

The effectiveness of lifestyle changes in the management of hypertension was rated as very high in 6.3%, high in 30.3%, neutral in 13.5%, low in 42.0%, and very low 7.9%. There was no difference between GPs and specialists. The proportion of patients with a blood pressure (BP) of 140–159 mmHg systolic and/or 90–99 mmHg diastolic without CV risk factors that will be initially treated by lifestyle changes only was 0% by 7.0% GPs, 1%–25% of patients by 66.4%, 26%–50% of patients by 17.4%, 51.75% by 6.2%, and 76%–100% of patients by 3.0%. In 4.6% of patients' target BP could be reached without additional medical intervention. In case that lifestyle changes only do not improve BP, 11.6% physicians initiate medical treatment after 1 month, 36.3% after 2–3 months, 40.3% after 4–6 months, 6.5% after 7–9 months, 4.1% after 10–12 months, and 1.2% after more than 12 months. Data from 18 GPs (2.6%) were missing [Figure 1].

An ACEI will be used as primary choice in patients with a high CV risk (77.7%), followed by the other parameters, such as metabolic syndrome (75.5%), age >65 years (75.4%), age <65 years (70.6%), lack of compliance (49.1%), and kidney failure (48.0%). The ranking of the mentioned parameters for the use of an angiotensin II receptor blocker (ARB) was metabolic syndrome (57.6%), high CV risk (53.2%), kidney failure (49.7%), lack of compliance (49.4%), age <65 years (46.3%), and >65 years (44.6%); for a β -blocker (BB) high CV risk (66.0%), age <65 years (21.9%), age >65 years (16.8%), kidney failure (16.2%), metabolic syndrome (8.7%), and lack of compliance (5.9%); for a CCB kidney failure (42.6%), metabolic syndrome (40.5%), age >65 years (32.2%), high CV risk (27.4%),

age <65 years (24.5%), and lack of compliance (20.6%); for a diuretic (D) age >65 years (30.8%), high CV risk (27.4%), kidney failure (24.6%), metabolic syndrome (12.9%), age <65 years (12.2%), and lack of compliance (10.2%) [Table 2].

When the target BP will not be reached by monotherapy, 45.6% increase the dosage after 2–4 weeks, 27.1% escalate to a combination of two or more antihypertensives after 2–4 weeks, 13.6% increase the dosage after a few months, 12.8% escalate to a combination of two or more antihypertensives after a few months, and 0.9% replace the substance.

When the target BP will not be reached by a loose combination therapy, 62.7% increase the dosages of the monocomponents, 29.9% substitute the monocomponents by an identical single pill (SP), and 7.3% replace the initial loose compounds.

In patients with mild hypertension (systolic BP [SBP] 140–159 mmHg, diastolic BP [DBP] 90–99 mmHg), 0.5% initiate medical treatment with a combination therapy in

patients without additional risk factors, 48.6% in patients with one or two risk factors, and 75.0% in patients with three or more additional risk factors.

In patients with moderate-to-severe hypertension (SBP >160 mmHg and DBP 100 mmHg), 34.5% initiate medical treatment with a combination therapy in patients without additional risk factors, 85.7% in patients with one or two risk factors, and 93.5% in patients with three or more additional risk factors.

There was a severe difference between specialists and GPs; 42.8% of specialists initiate combination treatment in patients suffering from moderate-to-severe hypertension without risk factors compared to 31.1% of GPs.

About 15.1% combine loose monocompounds only, 68.2% initiate combination treatment with a loose combination and switch than to a SP, and 16.7% initiate combination treatment with a SP. The advantages of a SP strategy are rated as follows: 96.0% improvement of patient's compliance, 59.0% better BP control, 31.5% reduction of CV risk, 20.3% less workload due to less prescriptions, 13.5% less *aut idem* discussion with the patients, and 12.9% optimization of patients contacts [Figure 2].

The main reasons for a lack of patient compliance in the judgment of the responders are seen in fear of side effects (75.8%), missing clinical signs that remind in the disease (74.1%), and complexity of treatment regimens (68.6%).

The decision for choosing a special substance is based on recommendations of clinical guidelines in 79.2%, comorbidities in 70.8%, restrictions of the regional board of panel in 38.5%, price in 28.8%, data from clinical trials in 22.1%, available dosages in 21.6%, recommendations from participation in scientific congresses in 21.3%, and recommendations of the pharmaceutical industry in 5.7%. The top three criteria are identical for specialists and GPs.

Table 1: Location of participants by area of regional board of panel doctors (Kassenärztliche Vereinigung)

Area of regional board of panel doctor	Percentage of participants
Westphalia-Lippe	10.5
North-Rhine	9.1
Rhineland-Palatinate	2.6
Baden-Württemberg	12.9
Hesse	4.7
Saxony-Anhalt	4.4
Schleswig-Holstein	2.8
Bavaria	15.5
Berlin	4.4
Saxony	4.2
Brandenburg	5.7
Thuringia	7.9
Lower Saxony	6.7
Saarland	2.2
Mecklenburg-West Pomerania	5.6
Bremen	0.4
Hamburg	0.3

Table 2: Medical rationale for the choice for an antihypertensive agent

Medical rationale	ARB (%)	ACEI (%)	BB (%)	CCB (%)	D (%)
Metabolic syndrome	57.6	75.5	8.7	40.5	12.9
High CV risk	53.2	77.7	66.0	27.4	27.4
Kidney failure	49.7	48.0	16.2	42.6	24.6
Lack of compliance	49.4	49.1	5.9	20.6	10.2
Age <65 years	46.3	70.6	21.9	24.5	12.2
Age >65 years	44.6	75.4	16.8	32.2	30.8

CV=Cardiovascular, ARB=Angiotensin II receptor blocker, ACEI=Angiotensin-converting enzyme inhibitor, BB=β-blocker, CCB=Calcium channel blocker, D=Diuretic

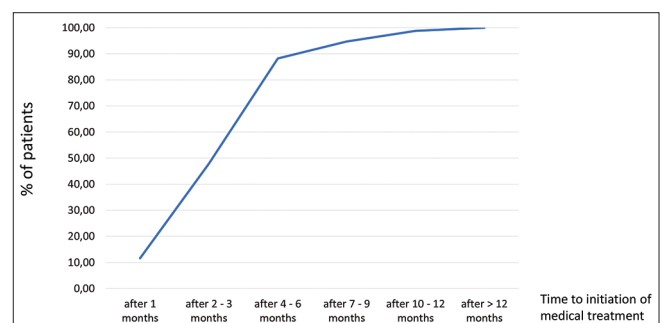


Figure 1: Time to initiation of medical treatment in patients with blood pressure (BH) of 140–159 mmHg systolic and/or 90–99 mmHg diastolic without cardiovascular risk factors that were initially treated by lifestyle changed only

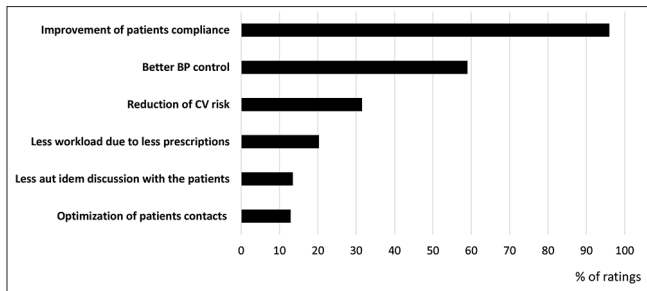


Figure 2: Advantages of a single pill (SP) treatment regimen (three different answers allowed)

Discussion

Due to the optimization of communication and analysis tools, a huge number of clinical findings is published everyday, which results to a gap between the volume of public health knowledge generated through clinical research and the application of the results into clinical practice.^[5] CPGs have been developed to increase clinical decision-making based on scientific evidence to reduce physician uncertainty.^[6] The ultimate goal of the implementation of research innovation is improving the quality of medical care, including particular health indicators and quality of life.^[5]

In 2013, the ESH and the ESC published new guidelines on AH following the previous guidelines jointly issued by the two societies in 2003 and 2007. Publication of a guideline was felt to be timely by the societies, because, over this period, important studies have been conducted and many new results have been published on both the diagnosis and treatment of individuals with an elevated BP, making refinements, modifications, and expansion of the previous recommendations necessary.^[7] Some of the new recommendations focused on the initiation of antihypertensive treatment, lifestyle management, a more liberal approach to initial monotherapy, and revised schema for prioritized two-drug combinations as well as a recommendation for a SP approach whenever possible.^[7]

The guidelines were adopted by the German association of hypertension and translated into national language.^[8] Guidance for choosing a special antihypertensive agent was given by a listing of side effects and advantages for the use under special clinical conditions.^[7]

We itemized the antihypertensives ARB, ACEI, BBr, CCB, and D and asked for a ranking of medical conditions/parameters such as high CV risk, metabolic syndrome, age >65 years, age <65 years, lack of compliance, and kidney failure. Hence, there was a ranking of these parameters given the antihypertensives, i.e., a conditional ranking of parameters for each and every single antihypertensive. In general, the use of the

substances was in line with the recommendations of the 2013 guidelines. However, we could identify a preference for the use of special classes of antihypertensive drugs as follows: ACEI will be used as primary choice in patients with a high CV risk, metabolic syndrome independent from age. The use of ARB was comparable to that of ACEI with a general lower percentage. An additional advantage was seen in patients with a lack of compliance, which might reflect a better side effect profile; BBs are preferred in patients under high CV risk. CCB were favored in kidney failure and metabolic syndrome and Ds in older patients and showed in general a lower percentage of use.

The 2013 recommendations were in favor to initiate medical treatment with a combination of two antihypertensive agents. However, they recommended to start with a monotherapy in patients with mild BP elevation/low-to-moderate CV risk and to start with a combination in patients with marked BP elevation/high-to-very high CV risk.^[7] This was followed by the majority of the physicians. Interestingly, a higher number of specialists started with a combination therapy which might reflect a better knowledge of published data favoring a combination therapy in patients suffering from AH.^[9] The 2013 ESH/ESC guidelines also recommend the use of combinations of two antihypertensive drugs at fixed doses in a single tablet, because reducing the number of pills to be taken daily improves adherence, which is unfortunately low in hypertension, and increases the rate of BP control.^[7] This is strongly followed by the majority of physicians 15.1% only combine loose monocompounds. The advantages of a SP strategy were also reflected in the answers given in the study; the main advantages were seen in an improvement of patient's compliance and a better BP control. Surprisingly, the main advantage of this strategy, the reduction of CV risk as a result of better adherence and better BP control was seen as an advantage in one-third only. This might reflect the guideline recommendations that describe a better adherence and a better BP control as advantage of the SP regimen only and do not point on one step further, the resulting reduction of CV risk.

Although the effectiveness of lifestyle changes on BP is well investigated, documented, and in detail explained by the guidelines,^[7,8] the results of our study suggest that this treatment option is not adequately adopted into clinical practice. The effectiveness of lifestyle changes in the management of AH was rated as very high in 6.3%, high in 30.3%, neutral in 13.5%, low in 42.0%, and very low 7.9%. There was no difference between GPs and specialists. The proportion of patients with a BP of 140–159 mmHg systolic and/or 90–99 mmHg diastolic without additional CV risk factors that will be initially treated by lifestyle changes only was surprisingly low as

well. In case that lifestyle changes only do not improve BP, 11.6% physicians initiate medical treatment after 1 month, 36.3% after 2–3 months, 40.3% after 4–6 months, 6.5% after 7–9 months, 4.1% after 10–12 months, and 1.2% after more than 12 months. This might reflect a lack of medical education regarding the topic of nonpharmacologic treatment during medical training of students as well as certified medical education (CME) during professional life. In addition, lifestyle changes require the patient's adherence.

A high percentage of GPs stated that their treatment decisions will be influenced by guideline recommendations. One reason might be the high quality of the methodology and scientific content of the current guidelines, which is a strong requirement for acceptance.^[10]

The European members of the task force in charge of the 2013 guidelines on hypertension have been appointed by the ESH and ESC, based on their recognized expertise. Each member was assigned a specific writing task, which was reviewed by three coordinators and then by two chairmen, one appointed by ESH and another by ESC. The text was finalized over approximately 18 months, during which the task force members met collectively several times and corresponded intensively with one another between meetings.^[7] This might reflect trust in the evidence of the recommendations. A full implementation of guidelines may also be prohibited by the restrictions of the regional board of panel. Clinical findings might be of benefit for the patient, but in some cases, not the cheapest way of treatment.

The lack of implementation of the recommended lifestyle changes might also be linked to a lack of experience. Prescription of nutritional education, e.g., is not part of the duties in a German GPs office and was limited in the past by health-care payers. One of the most common barriers to implementation found by Spallek *et al.* was difficulty in changing current practice model.^[11] A close cooperation with local health-orientated sports clubs could be an option to improve implementation of the recommendations for lifestyle changes. In addition, validated multimodal training programs, e.g., tailored to reduce weight or to improve CV fitness, should be promoted in the GPs office. This could be supported by practical recommendations in future guidelines.

There are some limitations of our study. We limited our questionnaire to 12 closed questions to make the participation and the analysis feasible. We focused on the main topics of the treatment guidelines. Therefore, the questions did not cover all aspects related to the transfer of guidelines into daily practice. A large number of participating physicians are visited on

a regular basis by pharmaceutical companies that promote antihypertensive medication. This might have led to a positive bias. When we started our survey, the ESH/ESC guidelines were still in place since 2013, the German adoption is available since 2015. Our study was not designed to register the time from publication to implementation, which might be another interesting topic due to the fact that the turnover for clinical guidelines in other indications is frequently not more than 2 years.

Our study was a first step to verify whether real-life daily practice is reflecting what is recommended in the guidelines.^[4] In this context, there are several further questions, which might be answered by future, larger investigations.

Conclusions

Medical treatment algorithm recommended by the 2013 ESC/ESH guidelines for the management of AH, adopted and published 2015 in Germany by the German association of hypertension (Deutsche Hochdruckliga, DHL) seem to be well accepted and established in GPs offices by assessment in 2018. The effects of lifestyle changes on BP are well investigated and documented. In contrast, the results of our study suggest that this is not sufficiently adopted into clinical practice, which might reflect a lack of CME regarding this topic.

When we started our survey, the European guidelines were still in place since 2013 with a German translation available since 2015. Our study was not designed to register the time from publication to implementation, which might be another interesting topic due to the fact that the turnover for clinical guidelines in other indications is usually not more than 2 years.

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Conflicts of interest

O. Randerath is employee of the Medical Department of APONTIS PHARMA GmbH and Co. KG, Monheim (Germany). All other authors declare no conflict of interest.

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