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DOI: 10.20514/2226-6704-2026-16-1-5-11
УДК 616.12-008.331.1-085.22-06-053.9
EDN: APSOHT

О.Н. Антропова, И.В. Осипова, Н.В. Пырикова

Федеральное государственное бюджетное образовательное учреждение высшего образования «Алтайский государственный медицинский университет» Министерства здравоохранения Российской Федерации, кафедра факультетской терапии и гериатрии, Барнаул, Россия

СТРАТЕГИЯ ДЕПРЕСКРАЙБИНГА АНТИГИПЕРТЕНЗИВНЫХ ПРЕПАРАТОВ У ОЧЕНЬ ПОЖИЛЫХ И ОСЛАБЛЕННЫХ ПАЦИЕНТОВ: ОБЗОР СОВРЕМЕННЫХ ДАННЫХ

O.N. Antropova, I.V. Osipova, N.V. Pyrikova

Federal State Budgetary Educational Institution of Higher Education «Altai State Medical University» of the Ministry of Health of the Russian Federation, Department of Faculty Therapy and Geriatrics Barnaul, Russia

Strategy for Depressing Antihypertensive Drugs in Very Elderly and Fragile Patients: A Review of Contemporary Data

Резюме

Антигипертензивные препараты снижают риск инсульта и сердечно-сосудистых заболеваний во всех возрастных группах. Однако, у пожилых и ослабленных пациентов антигипертензивное лечение связано с повышенным риском гипотонии, обморока, острого повреждения почек и гиперкалиемии, у таких пациентов риск нежелательных явлений может превышать пользу от антигипертензивного лечения, и для снижения этого риска предлагается отмена назначения препарата. Концепция депрескрайбинга антигипертензивных препаратов новая и многие практические аспекты требуют дальнейшего изучения в рандомизированных контролируемых исследованиях для определения долгосрочных эффектов, определяющих важные клинические результаты и качество жизни пожилых пациентов. Необходимо признать, что отмена антигипертензивных препаратов является областью с ограниченными доказательствами, с очень небольшим количеством клинических испытаний, оценивающих долгосрочные клинические эффекты. В данном обзоре рассмотрены обоснование и возможные препятствия к внедрению в клиническую практику контролируемой отмены антигипертензивных препаратов у лиц пожилого и старческого возраста. Приведены рекомендации по идентификации пациентов с высоким риском нежелательных явлений и алгоритму депрескрайбинга.

Ключевые слова: *артериальная гипертония, депрескрайбинг, пожилой и старческий возраст*

Конфликт интересов

Авторы заявляют, что данная работа, её тема, предмет и содержание не затрагивают конкурирующих интересов

Источники финансирования

Авторы заявляют об отсутствии финансирования при проведении исследования

Статья получена 21.03.2025 г.
Одобрена рецензентом 13.05.2025 г.
Принята к публикации 02.07.2025 г.

Для цитирования: Антропова О.Н., Осипова И.В., Пырикова Н.В. СТРАТЕГИЯ ДЕПРЕСКРАЙБИНГА АНТИГИПЕРТЕНЗИВНЫХ ПРЕПАРАТОВ У ОЧЕНЬ ПОЖИЛЫХ И ОСЛАБЛЕННЫХ ПАЦИЕНТОВ: ОБЗОР СОВРЕМЕННЫХ ДАННЫХ. Архивъ внутренней медицины. 2026; 16(1): 5-11. DOI: 10.20514/2226-6704-2026-16-1-5-11. EDN: APSOHT

Abstract

Article Title. Antihypertensive drugs reduce the risk of stroke and cardiovascular disease in all age groups. However, in elderly and frail patients, antihypertensive treatment is associated with an increased risk of hypotension, syncope, acute kidney injury and hyperkalemia; in these patients, the risk of AEs may outweigh the benefits of antihypertensive treatment, and drug withdrawal is proposed to reduce this risk. The concept of controlled withdrawal of antihypertensive drugs is new and many practical aspects require further study in randomized controlled trials to determine the long-

term effects on important clinical outcomes and quality of life in elderly patients. Given the limited evidence on long-term outcomes of controlled withdrawal of antihypertensive drugs, it must be recognized that withdrawal of antihypertensive drugs is an area of limited evidence, with very few clinical trials assessing long-term clinical effects. This review examines the rationale and potential barriers to the implementation of controlled withdrawal of antihypertensive drugs in the elderly. Recommendations for identifying patients at high risk of adverse events and a deprescribing algorithm are provided

Key words: *arterial hypertension, deprescribing, old and senile age*

Conflict of interests
The authors declare no conflict of interests

Sources of funding
The authors declare no funding for this study

Article received on 21.03.2025
Reviewer approved 13.05.2025
Accepted for publication on 02.07.2025

For citation: Antropova O.N., Osipova I.V., Pyrikova N.V. Strategy for Depressing Antihypertensive Drugs in Very Elderly and Fragile Patients: A Review of Contemporary Data. The Russian Archives of Internal Medicine. 2026; 16(1): 5-11. DOI: 10.20514/2226-6704-2026-16-1-5-11. EDN: APSOHT

EH — essential hypertension, BP — blood pressure, DS — deprescribing, AE — adverse event, ABPM — ambulatory blood pressure monitoring

Introduction

The elderly patient population is the quickest growing globally; based on 2024 estimates, the number of adults aged 60–79 years will increase from 760 million in 2015 to 1,646 million in 2050, or from 10.4 % to 17.0 % of the global population [1]. It is predicted that the number of adults aged over 80 years will increase from 126.6 million in 2015 to 430.3 million in 2050, or from 1.7 % to 4.4 % of the global population [2]. Approximately 65 % adults aged 60–79 years and 80 % aged over 80 suffer from essential hypertension (EH), defined as blood pressure (BP) ≥140/≥90 mm Hg or administered EH pharmacotherapy; thus, it is predicted that the number of adults aged 60–79 years with EH will increase approximately from 494 million in 2015 to 1.07 billion in 2050, while that among adults aged ≥80 years will increase from 101 million in 2015 to 344 million in 2050. Thus, the number of elderly persons with EH in 2050 will exceed the total number of adults with EH aged 30–79 years globally in 2010 [2].

Hypotensive drugs decreases the risks of the stroke and cardiovascular diseases in all age groups [3]. The hypotensive treatment benefits in elderly, including intensive hypotensive therapy, have been confirmed in large-scale randomized trials (HYVET, SPRINT, STEP); however, it is important to note that subjects with severe senile asthenia were not enrolled into trials [4, 5, 6]. As a result, hypotensive drugs are used in elderly, with over half of those being over 80 years of age [2].

Randomized controlled trials have demonstrated that hypotensive treatment is associated with enhanced risks of hypotension, syncope, acute kidney injury, and hyperkalemia; in general, this risk is very low, affecting 5 to 16 per 10,000 patients treated per year [2]. However, in elderly and fragile patients this risk significantly increases during hypotensive treatment (to 131 per 10,000 patients per year) [4]. This results from altered pharmacokinetic and pharmacodynamic reactions in elderly, as well as polypharmacy that increases the risk of drug-drug interactions, including serious adverse events (AEs). In such patients the risk of AEs may exceed the benefits of hypotensive treatment, while the drug discontinuation is proposed to decrease this risk [5].

This review analyzes the justification and possible obstacles to the implementation of controlled hypotensive drug discontinuation among elderly and senile patients into clinical practice. Recommendations concerning the identification of patients with a high risk of adverse events and the deprescribing (DS) algorithm are provided.

Deprescribing Justification And Challenges

DS (drug discontinuation) presumes the systemic process of controlled discontinuation or reduction of drug administration under the physician's surveillance with the purpose of managing polypharmacy, decreasing drug-associated issues, and improving the patient treatment results [7]. A small, but growing amount of evidence analyzing the feasibility and safety of hypotensive drug discontinuation in elderly patients exists. Although short-term evidence confirm this, the long-term DS benefits and risks are indefinite.

The DS issue importance is underlined by the results of a secondary cross-sectional data analysis from 4 cohort studies among the nursing home dwellers in Australia, China, Japan, and Spain. In total 84.7 % non-fragile, 95.6 % fragile patients, and 90.6 % patients with severe senile asthenia were administered at least 1 drug corresponding to the STOPP criterion, with the most common being hypotensive drugs (from 53.0 % in China to 73.3 % in Australia). The use of hypotensive drugs was

more common among more fit patients, with the prevalence ratio (PR) of 1.15 (95 % CI 1.06–1.25) [8].

The majority of EH clinical guidelines are primarily aimed at the hypotensive treatment initiation and enhancement, with very few guidelines on the discontinuation of hypotensive drugs [9]. The discontinuation of drugs for the treatment of cardiovascular risk factors was included into several clinical guidelines on primary care in diabetes mellitus; however, it is hard to implement [10, 11]. New European EH guidelines consider for the first time the possibility of reducing hypotensive drugs in elderly fragile patients with BP <120 mm Hg or with severe orthostatic hypotension, although they do not propose specific discontinuation strategies due to the lack of data on the optimal process and possible results [9], so it is often difficult for physicians to implement DS into routine practice [12].

DS during EH treatment in elderly is justified based on several studies. The long-term 4-year randomized trial OPTiMISE (n=6,194) has demonstrated that the reduction of drug administration is possible in over half of patients aged over 80 years with SBP below 150 mm Hg without any evidence of harm concerning hospitalization or all-cause mortality. These results have demonstrated that the discontinuation of hypotensive drug may be a safe attempt to decrease polypharmacy in elderly patients with controlled BP [7]. A cohort study that enrolled nursing home dwellers aged over 65 years has demonstrated that DS (reduction of the total number of hypotensive drugs or drug dose decrease by 30 % maintained for at least 2 weeks) is associated with a small cognitive decline, especially in persons with dementia [13]. The MINOR clinical trial that enrolled elderly patients with the symptoms of hypotension has analyzed the possibilities of controlled hypotensive drug discontinuation based on the ABPM (ambulatory blood pressure monitoring) evaluation. A significant decrease in the number of drugs administered (-28.6 %; P <0.001) and a decreased rate of hypotension symptoms was confirmed in the DS group vs. the control group (64.9 % vs. 20 %) (P <0.001) [14]. 17.8 % patients had their hypotensive drugs discontinued within 12 weeks in the observational trial that enrolled 13,096 long-term care facility residents using hypotensive drugs. The cumulative 2-year hospitalization rate with the stroke or myocardial infarction was similar among residents that continued treatment or underwent DS [15].

However, one cannot state that the data obtained were unanimous. For example, in the DANTON study that enrolled 205 subjects randomized into the groups of hypotensive treatment discontinuation (n=101) or continuing regular hypotensive treatment (n=104), serious adverse events (AEs) during the 16-week follow-up were observed in 36 % (treatment discontinuation) and 24 % (regular therapy) patients, with the adjusted hazard ratio of 1.65 [95 % CI 0.98–2.79]. Authors concluded that hypotensive treatment discontinuation was not safe and beneficial enough to recommend it in elderly persons with dementia [16].

Observational studies have showed that 3 out of 4 patients indicated less strict drug therapy do not discontinue cardiovascular or antidiabetic drugs [17], which may lead to the risk of preventable AEs. Several obstacles were detected for the DS of cardiometabolic drugs [18]. Physicians had difficulties with their decisions due to the lack of evidence regarding potential benefits and risks of discontinuing cardiometabolic drugs. Besides, sufficient communicative skills and tools have not been developed to involve elderly and fragile patients into the discussion of potential benefits and risks [19]. Patients possibly evaluate the benefits and harm of hypotensive treatment differently based on their values, preferences, and specific circumstances [20]. Thus, DS should include the mutual decisions made with the patients and their caregivers. The final objective is to optimize patient care by weighing the advantages and drawbacks of continuing treatment individually for each patient.

The Dutch Multicomponent CO-DEPRESCRIBE Program was started in 2024 with the purpose of educating communications concerning the discontinuation of cardiometabolic drugs in elderly patients within the primary care settings. The program aim is to let physicians initiate and arrange comprehensive consultations (accounting for the potential benefits and risks of discontinuing cardiometabolic drugs, accounting for the functional status, attitude, and the patient's drug treatment experience) in patients aged 75 years and over regarding the discontinuation of cardiometabolic drugs [21].

Deprescribing Algorithm

The protocol for hypotensive drug discontinuation based on the CEASE model [22] was proposed in 2015 and includes several steps:

C (**current drugs**) — current drug therapy of the patient and indications to the drug use;

E (elevated risk) — evaluation of the drugs administered for the risk of adverse effects;

A (assess) — assessment of the benefit-risk ratio for each drug;

S (sort and prioritise) — ranking the priorities of drug discontinuation depending on the benefits, harm, discontinuation simplicity, and patient preferences;

E (eliminate) — DS and patient condition monitoring after the drug discontinuation.

The modern algorithm of controlled hypotensive drug discontinuation presumes several key steps, focusing on the patient characteristics and thorough monitoring of BP and adverse effects.

First Step: Identification of Patients with a High Risk of Adverse Events (AEs)

Adverse effects of hypotensive treatment includes hypotension, syncope, falls, fractures, acute kidney injury, and electrolyte disorders [23, 24]. The largest relative association with hypotensive treatment in randomized clinical trials was established by BP decrease (hypotension and syncope). Several conditions and factors may lead to a higher risk of adverse events (Table 1).

Accounting for the complex EH treatment in elderly patients and multiple AE risk factors, it is feasible to evaluate individual risks using special tools that can help in making physician decisions. The STRATIFY-Falls tool to evaluate the risk of hospitalization or death resulting from serious falls within the next 1, 5, 10 years uses the model that includes age, gender, ethnicity, history of falls, stroke and multiple sclerosis, senile asthenia, and drug use [25]. This tool provides the personalized evaluation of the AE risk which may directly correlate with the cardiovascular risk. However, this tool has limitations when used among patients with a very high risk of adverse events, and no threshold has been defined for a risk that can be considered sufficiently high to justify DS.

Second Step: BP Evaluation

Before discontinuing treatment, it is important to confirm that the patient's BP is controlled below the recommended values (<150 mm Hg in patients over 80 years, <140 mm Hg in those aged 75–79 years) [9]. Russian EH guidelines lack statements about such values, while the regular evaluation of the status and AEs is recommended along with an individual approach in patients with impaired self-care abilities and dementia [25].

In elderly patients with EH and syncope, hypotensive drug discontinuation with systolic BP elevation by 12 mm Hg and the absolute 24-hour MBP elevation to 134 mm Hg prevented falls, which, according to authors, was an optimal DS target [26].

Third Step: DS Group Identification

To determine the candidate drugs for discontinuation, one should thoroughly analyze the current drug regimen using STOPP (Screening Tool of Older Person's Prescriptions) / START (Screening Tool to Alert Doctors to Right Treatment) criteria (Version 3, 2023) [27] and Beer's criteria of the American Geriatric Society [28]. STOPP/START criteria were developed as a tool to detect potentially non-recommended or irrationally administered drugs, as well as to detect the so-called "missed" administrations, i.e. those with sufficient efficacy data in a specific disease, but which were not administered earlier due to any cause. An Expert Group (11 experts from 8 European countries) has harmonized the third version that contains already 133 STOPP and 57 START criteria [28]. The number of published studies ¬using STOPP/START criteria is stably growing since 2008, reflecting their practical clinical significance in many countries [17].

STOPP criteria include drug products potentially not recommended for use in patients aged 65 years or older, when the risks of their use overweigh the expected benefits. START criteria include drug products to be considered if they were not administered earlier regardless of contraindications and if the clinical status of the elderly patient is not "end-of-life", i.e. not presuming the focus on palliative pharmacotherapy. It is presumed that

Table 1. *Risk factors for adverse events during antihypertensive treatment in the elderly*

Risk factors for adverse events (AE)	The case for deprescribing
Advanced age	Age-related changes in pharmacokinetics and pharmacodynamics predispose to the development of AE. Polymorbidity and polypharmacy are accompanied by a high risk of drug interactions and AE.
Dementia	The high risk of syncope and falls is exacerbated by sedatives and antipsychotics. Anticholinesterase inhibitors may cause bradycardia, especially with beta blockers.
Chronic kidney disease	Impaired drug excretion leads to an increased risk of adverse events and acute kidney injury.
History of AE	A history of previous AE determines a high risk of future complications.
Low blood pressure	Patients with SBP <120 mmHg are at risk of hypoperfusion and syncope-associated AE/
Severe frailty	High risk of adverse events that may lead to hospitalization, decreased autonomy.
Polypharmacy	Polypharmacy may be justified and even in patients with a high risk of AE or inadequate when the risk of AE exceeds the benefit. It is necessary to establish the priority of prescribing medications.

the physician administering drugs analyzes all specific contraindications to their administration before recommending the pharmacotherapy to an elderly patient.

STOPP/START criteria are grouped by organ systems, including additional sections devoted to DPs that increase the risk of falls in elderly patients, use of analgesics and DPs with antimuscarinic/anticholinergic properties, and immunization.

If the indications to DS of hypotensive drugs have been confirmed, it is recommended to discontinue them in the order reverse to the treatment recommended [9]. Drugs not recommended for elderly persons, i.e. loop diuretics, aldosterone antagonists, centrally acting hypotensive drugs, peripheral vasodilators, alpha-blockers, may be discontinued first. Concerning other drugs, beta-blockers are considered for discontinuation first, followed by thiazides or thiazide-like diuretics, or ACE inhibitors/angiotensin-II receptor blockers, and (finally) calcium channel blockers [24].

Fourth Step: Drug Discontinuation And Thorough Monitoring of Results

The DS process for hypotensive drugs is individual, although a practical algorithm exists [24]:

Doses of the following drug classes are discontinued/reduced (in the order preferred): diuretics (thiazides/thiazide-like, i.e. hydrochlorothiazide, indapamide) is the most common group to be discontinued; calcium channel blockers; ACE inhibitors or angiotensin-II receptor blockers; beta-blockers were discontinued less common due to comorbidities (CAD, AFib).

The DS procedure is selected at the physician's discretion — complete discontinuation of a single drug or its 25–50 % dose reduction.

During the discontinuation process, hypotensive drugs may be discontinued one by one with 4-week intervals.

Regular follow-up is required with the evaluation of AEs associated with the drug discontinuation (uncontrollable EH, palpitations, edema after discontinuing diuretics) along with BP measurement. If systolic BP remains below 150 mm Hg in 12 weeks, deprescribing is considered successful. If BP has become uncontrollable, one should consider the possibility of a repeated administration of a drug discontinued earlier in a lower dose (if possible) or recommend other non-drug approaches to blood pressure reduction.

The OPTIMISE (Optimising Treatment for Mild Systolic Hypertension in the Elderly) trial showed that the total AE rate in the DS and standard treatment groups was similar (12.1 % and 12.5 %, respectively (p=0.92) [7]. The DANTON (Deprescribing and Adverse events in New Users of Two or More Old-age Negative Agents) trial demonstrated that the AE (BP fluctuations, tachycardia, edema) rate in the setting of hypotensive drug DS was 10–15 %. 18–25 % patients required complete or partial resumption of the discontinued drug within 6–12 months after DS [16].

DS studies did not present detailed data on the association of specific AEs and the discontinuation of specific hypotensive drug classes. However, based on the general pharmacology principles, one can define expected AEs during the DS process by the drug classes.

Conclusion

The concept of hypotensive drug DS is new, and many practical issues required further analysis in randomized controlled trials to determine the long-term effects on important clinical results and the quality of life of elderly patients. It should be underscored that hypotensive drug discontinuation is a sphere with limited evidence and very few clinical trials evaluating long-term clinical effects. This review has summarized the current data on benefits and risks of hypotensive drug discontinuation in elderly patients, describing the practical DS algorithm.

Table 2. *Adverse events potentially associated with discontinuation of specific classes of antihypertensive drugs*

Drug classes	Potential adverse events after discontinuation
Diuretics	Increased blood pressure, edema (due to decreased sodium excretion). Hypokalemia (if the diuretic is discontinued in patients with initially low potassium).
Calcium channel blockers	Reflex tachycardia (due to decreased vasodilation). Deterioration of blood pressure control (especially in patients with initially high pulse pressure).
ACE inhibitors/sartans	Increased edema (rare if calcium channel blockers were continued in treatment). Increased creatinine (if there was a decrease in glomerular filtration rate and ACE inhibitors/sartans played a nephroprotective role).
Beta blockers	Tachycardia, increased blood pressure (if indicated — coronary heart disease, atrial fibrillation). Exacerbation of angina (in patients with coronary heart disease). Consider reducing the dose first before completely discontinuing the drug to avoid recurrent adrenergic hypersensitivity.

Вклад авторов:

Все авторы внесли существенный вклад в подготовку работы, прочли и одобрили финальную версию статьи перед публикацией

Антропова О.Н.: разработка концепции и дизайна работы, написание статьи, окончательное утверждение для публикации рукописи, проверка критически важного интеллектуального содержания, автор согласен быть ответственным за все аспекты.

Осипова И.В.: поиск информации, анализ и обобщение данных литературы, написание статьи.

Пырикова Н.В.: сбор данных; анализ и обобщение данных литературы; составление таблиц, подготовка статьи к публикации.

Author Contribution:

All the authors contributed significantly to the study and the article, read and approved the final version of the article before publication

Antropova O.N.: development of concept and design of the work, writing of the article, final approval of the manuscript for publication, review of critical intellectual content, the author agrees to be accountable for all aspects.

Osipova I.V.: information search, analysis and generalization of literature data, writing an article.

Pyrikova N.V.: data collection; analysis and summarization of literature data; compilation of tables, preparation of the article for publication.

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Информация об авторах

Антропова Оксана Николаевна — д.м.н., профессор кафедры факультетской терапии и гериатрии ФГБОУ ВО «Алтайский государственный медицинский университет» Министерства здравоохранения РФ, Барнаул, e-mail: antropovaon@mail.ru, ORCID ID: https://orcid.org/0000-0002-6233-7202.

Осипова Ирина Владимировна — д.м.н., заведующий кафедрой факультетской терапии и гериатрии ФГБОУ ВО «Алтайский государственный медицинский университет» Министерства здравоохранения РФ, Барнаул, e-mail: i.v.osipova@gmail.com, ORCID ID: https://orcid.org/0000-0002-6845-6173)

Пырикова Наталья Викторовна — д.м.н., профессор кафедры факультетской терапии и гериатрии ФГБОУ ВО «Алтайский государственный медицинский университет» Министерства здравоохранения РФ, Барнаул, e-mail: allinatali@mail.ru, ORCID ID: https://orcid.org/0000-0003-4387-7737.

Author information

Oksana N. Antropova — MD, PhD, Professor of the Department of Faculty Therapy and Geriatrics of the Altai State Medical University of the Ministry of Health of the Russian Federation, Barnaul, e-mail: antropovaon@mail.ru, ORCID ID: https://orcid.org/0000-0002-6233-7202.

Irina V. Osipova — MD, PhD, Head of the Department of Faculty Therapy and Geriatrics of the Altai State Medical University of the Ministry of Health of the Russian Federation, Barnaul, e-mail: i.v.osipova@gmail.com, ORCID ID: https://orcid.org/0000-0002-6845-6173

Natalya V. Pyrikova — MD, PhD, Professor of the Department of Faculty Therapy and Geriatrics of the Altai State Medical University of the Ministry of Health of the Russian Federation, Barnaul, e-mail: allinatali@mail.ru, ORCID ID: https://orcid.org/0000-0003-4387-7737.

Автор, ответственный за переписку / Corresponding author