INPLASY

Efficacy and safety of standard treatment protocols for blood pressure reduction compared with usual care: a systematic review and meta-analysis of randomised trials

INPLASY202380021
doi: 10.37766/inplasy2023.8.0021
Received: 04 August 2023
Published: 04 August 2023

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ADMINISTRATIVE INFORMATION

Support - India Alliance: Department of Biotechnology, Government of India, and the Wellcome Trust, UK.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380021

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 August 2023 and was last updated on 04 August 2023.

INTRODUCTION

Review question / Objective The aim of this systematic review and meta-analysis is to evaluate the efficacy and safety of standard treatment protocols for blood pressure reduction compared with usual care.

Rationale Globally, hypertension continues to be the leading preventable risk factor for cardiovascular diseases, premature death, and disability. There are large gaps in the diagnosis, awareness, treatment, and control of hypertension. Despite the availability of proven effective pharmacological and non-pharmacological therapies, less than half of treated individuals achieve guideline recommended blood pressure (BP) targets. To address some of the key barriers for hypertension control, standard treatment protocols (STPs) have been proposed as a strategy to guide hypertension treatment, particularly in the primary health care settings. STPs list, in a step-wise manner, the preferred pharmacological and non-pharmacological treatments for a health condition in a specific health system. Each STP includes the name, dosage form, strength, average dose (paediatric and adult), number of doses per day, and number of days of treatment. STPs contribute to streamlining care, simplify treatment options, reduce clinical variability outside the scope of evidence-based medicine, facilitate drug procurement, facilitate team-based care, and improve patients' adherence to medicines. As such, STPs have the potential to improve treatment and control of hypertension globally. There has been no review quantifying the effects of hypertension STPs (henceforth referred as STPs) on BP. We, therefore, aimed to evaluate, among patients with hypertension, BP-lowering efficacy and safety of STPs compared to usual care.

Condition being studied Hypertension.

METHODS

Search strategy A systematic literature search will be performed in Embase (from inception to January 10, 2022) and MEDLINE (from inception to January 10, 2022), using a systematic search strategy for identifying relevant RCTs. Additional sources of search included review of references of five previous relevant systematic reviews of hypertension control interventions.

Embase Classic + Embase (1947 to 2022 January 10)
Searches Results
1 (treat* adj4 protocol).tw. 36554
2 (treat* adj4 algorithm).tw. 11742
3 (treat* adj4 schedule*).tw. 16770
4 flow chart.tw. 2184
5 flowchart.tw. 2043
6 or/1-5 68606
7 hypertensi*.ti. 286774
8 blood pressure.ti. 89907
9 antihypertensive*.ti. 19331
10 or/7-9 372636
11 6 and 10 697
12 limit 11 to (human and english language) 526

Search strategy for systematic reviews: Ovid MEDLINE(R) (1947 to 2022 January 10)
Searches
1 hypertension
2 antihypertensive
3 antihypertensiv*
4 anti-hypertensiv*
5 anti?hypeten*
6 anti-hyperten*
7 blood pressure lowering
8 BP lowering
9 BPLD
10 or/1-9
11 clinicaltrial[Filter]
12 randomizedcontrolledtrial[Filter]
13 exp evaluation studies/
14 (comparative stud*).tw
15 (experimental).tw.
16 (control* clinical trial*).tw.
17 (random* control* trial).tw.
18 (rct).tw.
19 random*).tw.
20 (clinical adj2 trial$).tw.
21 control* trial$.tw.
22 or/11-21
23 India
24 Andaman
25 Nicobar
26 Andhra Pradesh
27 Arunachal Pradesh
28 Assam
29 Bihar
30 Chandigarh
31 Chhattisgarh
32 Dadra and Nagar Haveli
33 Daman and Diu
34 Delhi
35 Goa
36 Gujarat
37 Haryana
38 Himachal Pradesh
39 Jammu and Kashmir
40 Jharkhand
41 Karnataka
42 Kerala
43 Lakshadweep
44 Madhya Pradesh
45 Maharashtra
46 Manipur
47 Meghalaya
48 Mizoram
49 Nagaland
50 Orissa
51 Odisha
52 Puducherry
53 Punjab
54 Rajasthan
55 Sikkim
56 Tamil Nadu
57 Telangana
58 Tripura
59 Uttar Pradesh
60 Uttarakhand
61 West Bengal
62 or/23-61
63 22 and 62
64 Protocol
65 63 and 64
66 Limit 65 to humans, english, alladult, clinicaltrial, randomizedcontrolledtrial.

Participant or population Adults with hypertension.

Intervention Standard treatment protocol, defined as series of steps recommended for the pharmacological management of hypertension covering the information on patient group (e.g., age, condition, race) for whom the protocol is applicable, BP thresholds for initiating and intensifying pharmacological treatment, target BP, and BP-lowering class and/or drugs to be used at each step.

Comparator Usual care as defined by the included studies.

Study designs to be included Randomized clinical trials.

Eligibility criteria Inclusion criteria: Participants: adults (≥18 years of age) with hypertension (SBP ≥140 mmHg and/or DBP ≥90 mmHg; or taking antihypertensive drugs or had hypertension as defined by the study). Intervention: Standard treatment protocol as the only intervention or as co-intervention. Comparator: Usual care. Outcomes: data reported to calculate difference in BP reduction between the groups. Study type: randomized clinical trials. Exclusion criteria: 1. Trials with participants age <18 years 2. Trials not comparing an STP with usual care.3. Trials focusing on specific drugs (e.g., industry trials) or of non-pharmacological interventions only. 4. Trials published in non-English language.

Information sources Embase, MEDLINE , references of five previous relevant systematic reviews of hypertension control interventions.

Main outcome(s) i. Difference in mean change in systolic and diastolic BP from baseline to maximum follow-up available in included trials.

Additional outcome(s)
i. Proportion of patients achieving BP control in each group
ii. Incidence to withdrawal of treatment due to adverse events
iii. Incidence of treatment-related adverse events
iv. Incidence of adverse events.

Data management Records retrieved from the search will be reviewed by one author to assess eligibility for inclusion. A second author reviewed excluded records to ensure no eligible records will be excluded, and inclusion of trials will be based on consensus. From the included trials of STPs, we collected data on study design, participant characteristics, intervention, comparator, sample size, outcomes, and also characteristics of the STP. For trials that did not report variability data, it will be imputed from the average of SDs from other included studies. Data will be extracted by one author and a second author revised them for accuracy.

Quality assessment / Risk of bias analysis Risk of bias in included trials will be assessed using Cochrane Risk of Bias tool version 1.0.

Strategy of data synthesis Continuous outcomes of difference in change in BP will be assessed using DerSimonian and Laird random-effects model, and dichotomous outcomes of safety will be assessed using DerSimonian and Laird inverse variance random-effects model. Heterogeneity in effect estimate across included trials will be assessed by Q statistics and quantified using the I2 statistics (heterogeneity due to true variance in effects across trials). All meta-analyses will be performed using Comprehensive Meta-Analysis (CMA) v2.0 (Biostat Inc., Englewood, NJ, USA).

Subgroup analysis None.

Sensitivity analysis Excluding studies where STP was a co-intervention, and those with imputed standard deviation for BP.

Language restriction Only trials published in English language will be included.

Country(ies) involved India.

Keywords Standard treatment protocol; anti-hypertensive agents; diastolic blood pressure; systolic blood pressure; pharmacological therapy; meta-analysis.

Dissemination plans The systematic review and meta-analysis will be published in a peer-reviewed hypertension or cardiology journal.

Contributions of each author
Author 1 - Gautam Satheesh - GS performed the abstract and full-text screening, extracted the data, conducted the analyses, and interpreted the findings.
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Author 2 - Rupasvi Dhurjati - RD performed the abstract and full-text screening, extracted the data, and conducted the analyses.
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