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Original Article

Hypertension control in Kerala, India: A prescription-based study at primary and secondary level health care institutions

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ABSTRACT

Objective: We undertook a prescription-based study to identify the provider and institution-level factors related to achieving guideline-recommended control of hypertension and diabetes mellitus in Kerala, India.

Methods: This cross-sectional study in primary and secondary care hospitals in Kerala included both public and private institutions. One practitioner was selected from each institution. Data on institutional and provider factors were collected using a structured questionnaire. Prescriptions were photographically captured and data on disease status and drugs prescribed were recorded. Factors associated with disease control were identified using binary logistic regression.

Results: Totally 4679 prescriptions were included for analysis. For hypertension-only patients, control levels were 31.5% and was significantly higher in public hospitals (Adjusted odds ratio (AOR) 1.96, 95% confidence intervals (CI) 1.50–2.57). Among patients with diabetes only, diabetes control was seen in 36.6%. When both conditions were present, control was achieved in only 17.0% patients. Being prescribed two or more drugs indicated lower control, whatever the respective condition. Among antihypertensive prescriptions rationality of 26.7% were questioned, such as lack of Renin Angiotensin System (RAS) inhibitor in diabetic hypertensives, dual RAS blockage, and indication for beta-blocker monotherapy.

Conclusions: In this prescription-based study in Kerala, India, a majority of hypertensive patients did not have controlled blood pressure levels, particularly if diabetes coexisted. This has serious implications as Kerala is the state with the highest burden of hypertension in India. Several prescription patterns were of questionable rationality. Further research and actions on rationality of anti-hypertensive prescriptions and barriers to treatment intensification is warranted.

1. Introduction

Kerala state in India, with an estimated population of 33,387,677 in 2011,[1] experiences high cardiovascular mortality[2] and high prevalence of hypertension and diabetes mellitus.[3] Achieving guideline recommended control of blood pressure (BP) and blood sugar is very complex.[4] Multiple factors at various levels may affect blood pressure control in populations.[5,6] Recent studies have examined individual level factors predicting hypertension control.[7] Institutional level[8] and provider level[9] factors too may affect such outcomes. Studies based on medical prescriptions may offer promise of quick evaluation of disease control in populations.[10] A good prescription should help attain optimal treatment targets while being acceptable, affordable and safe.[11] Electronic health records may facilitate interventions based on prescriptions.[12] We undertook a study based on medical prescriptions to identify the

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provider and institution level factors predicting control of hypertension and diabetes mellitus in Kerala, India.

2. Material and methods

2.1. Study design and participants

The detailed methodology of the study has been published earlier.[13] We used a cross-sectional design wherein 344 doctors from primary and secondary level institutions (public – 182, private - 162) from seven districts in Kerala were recruited. Prescriptions issued by the selected doctor in a period starting six months prior to the date of consent to six months after that date were included.

2.2. Data collections procedures

Trained interviewers used a structured questionnaire to capture provider characteristics (demographics, professional qualification, experience, patient density, continuing medical education activities, self-reported prescription standards), and institutional variables (urban or rural, quality certifications, use of patient management software, institutionally acknowledged guidelines for NCD management). Prescriptions for hypertension, diabetes or both were captured photographically. Prescription quality was determined using a checklist and this was reported in the earlier publication.[13] Hypertension control implied a BP < 140/90 mm Hg. Diabetes mellitus control was defined as fasting blood sugar <126 mg/dl, post-prandial blood sugar or random blood sugar <200 mg/dl or HbA1C < 6.5%.

2.3. Statistical analysis

The unit of analysis was the prescription rather than the patient. Stata Statistical Software: Release-14 was used for statistical analysis. Binary logistic regression analysis was used to generate odds ratios and 95 percent confidence intervals (95% CI). Variables that had a p value below 0.05 were considered significant. For prescriptions for both hypertension and diabetes, multinomial logistic regression analysis was attempted initially followed by binary logistic regression with “both hypertension and diabetes controlled” as the predicted outcome.

2.4. Rationality of prescriptions

We did not have sufficient details to assess rationality of prescriptions comprehensively. An expert in Clinical Pharmacology flagged possibly irrational drugs or combinations, and these were reported.

2.5. Ethical considerations

We obtaining written informed consent from participating doctors. Prescription data were deidentified during data entry. The study was cleared by the Institutional Ethics Committee of Health Action by People, Thiruvananthapuram, (Reference: IEC No EC I/JUNE/2014/HAP) as per relevant national guidelines.[14]

3. Results

3.1. Summary of prescriptions studied

The study obtained 9199 prescriptions from 344 participating doctors, with at least 25 prescriptions from each doctor. Prescriptions were categorized as hypertension only ($n = 3373$), both diabetes and hypertension (3096), and diabetes only ($n = 2730$). Control status could be determined effectively from 4679 prescriptions. Baseline characteristics of these prescriptions are given in Table 1. Several variables like anthropometry and associated comorbidities were missing from most prescriptions. Some prescriptions did not have information on patients age (4.7%). Many did not mention sex of the patient (41.8%). Around half of the prescriptions were of good quality.

Table 2 shows the proportion of prescriptions indicating control levels, and average blood pressure readings and number of drugs. Only about a third hypertensive patients had controlled BP levels. If they had both hypertension and diabetes, less than a fifth achieved control levels for both conditions. The supplementary file contains frequencies and summaries of regression models for each condition.

3.2. Factors associated with hypertension control

For patients with hypertension alone, prescriptions from public hospitals predicted twice better control, while having two or more antihypertensive drugs, or prescription generated using patient management software had significantly lower odds of control in multivariable analysis, as shown in Table 3. When hypertension existed along with diabetes, control of both conditions was highest if the prescription was from an institution with a quality certification (41, 22.8%). The lowest proportion of control of both conditions was in those patients who had a prescription of two or more antihypertensive drugs (35, 11.08%). On multivariable analysis, having more than one drug for each condition remained the only variable significantly associated with poor control of both the conditions.

3.3. Rationality of prescriptions

Fig. 1 shows the frequent drugs prescribed for hypertension. Calcium channel blockers were the commonest, either as monotherapy or with a Renin Angiotensin System Inhibitor (RASI) group drug. Metformin was the commonest drug prescribed for diabetes mellitus – either alone, or with sulfonylureas. The proportion of prescriptions with statins was 20.9% (hypertension only – 23.6%; both hypertension and diabetes – 26.2%; diabetes only – 18.1%).

Table 4 shows the prescriptions patterns flagged as potentially irrational. Of the 3454 hypertension prescriptions (with/without diabetes), 921 (26.7%) were potentially irrational. Beta-blocker monotherapy in the absence of a specific indication was the commonest (Overall 398, 11.5%; hypertension alone 269, 11.3%; hypertension with diabetes 129, 12.0%). Nearly half of the patients with both hypertension and diabetes had antihypertensive monotherapy with non-RASI drugs. A few prescriptions had dual Renin Angiotensin System (RAS) blockage either as one Angiotensin Converting Enzyme Inhibitor (ACEI) with one Angiotensin Receptor Blocker (ARB) or two ARBs. More than a third of the patients with hypertension and diabetes were not receiving RASI. Frusemide monotherapy was seen in six prescriptions.

4. Discussion

In our cross-sectional prescription-based study in Kerala on control of hypertension and diabetes, about two-thirds of patients with hypertension or diabetes had not achieved control levels. Control levels were poorer if both hypertension and diabetes were present. Lowering of BP and blood sugar is extremely important for Kerala,[3] which has high all-age Disability Adjusted Life Year (DALY) rates for cardiovascular and cerebrovascular disease.[15] The huge potential for vascular benefits of lowering blood pressure below

Table 1
Baseline characteristics of the 4679 prescriptions studied.

Variable	Categories	Number	Proportion
Provider characteristics			
Age of doctor (years)	20–40	2424	51.8%
	41–80	2255	48.2%
Sex of doctor	Female	2190	46.8%
	Male	2489	53.2%
Level of professional training	MBBS	2437	52.1%
	Specialist	2242	47.9%
Experience of doctor (years)	0–30	3948	84.6%
	31–60	721	15.4%
Average patient density/day	0–80	2318	49.5%
	81–250	2361	50.5%
Attended at least one Continuing Medical Education programme	No	1496	32.0%
	Yes	3183	68.0%
Attended online course	No	3602	77.0%
	Yes	1077	23.0%
Active subscription to journals	No	3351	71.6%
	Yes	1328	28.4%
Standard of doctor's prescription practice	Low	2242	47.9%
	High	2437	52.1%
Quality of prescriptions	Poor	2465	52.7%
	Good	2214	47.3%
Institutional characteristics			
Institution location	Urban	1123	24.0%
	Rural	3556	76.0%
Type of hospital	Private	2188	46.8%
	Public	2491	53.2%
Quality certification for institution	No	4005	91.9%
	Yes	351	8.1%
Presence of patient management software	No	4375	93.5%
	Yes	304	6.5%
Presence of NCD guidelines[a]	No	1679	35.9%
	Yes	3000	64.1%
Variables from prescriptions			
Patient age (years)	≤60	2038	45.7%
	>60	2419	54.3%
Sex of patient	Female	1673	61.4%
	Male	1050	38.6%
Antihypertensive/antidiabetic medications in prescriptions	None	281	6.0%
	Any one	4398	94.0%

[a] If doctors acknowledged that their hospital had displayed/circulated standard non-communicable disease management guidelines.

Table 2
Proportion of prescriptions indicating control for hypertension or diabetes or both, and averages of blood pressure readings and number of drugs prescribed.

	HTN only	HTN + DM	DM only
Number of prescriptions studied	2375	1079	1225
Number, % Controlled (95% CI)	749	358[a]	448
	31.5% (29.7–33.4)	33.2 (30.4–36.0)	36.6% (33.9–39.3)
		183[b]	
		17.0 (14.7–19.2)	
Systolic blood pressure – Mean (SD)			
Controlled	122.9 (9.5)	123.0[a] (9.1)	–
		122.8[b] (9.4)	
Uncontrolled	151.6 (16.7)	151.9 (17.4)	–
Diastolic blood pressure – Mean (SD)			
Controlled HTN	76.0 (6.5)	77.4[a] (5.6)	–
		76.9[b] (6.4)	
Uncontrolled HTN	87.7 (10.0)	86.8 (9.6)	–
Number of drugs – Mean (SD)			
Controlled HTN	1.1 (0.6)	1.1 (0.6)	–
Uncontrolled HTN	1.3 (0.7)	1.3 (0.7)	–
Controlled DM	–	1.4 (0.7)	1.6 (0.8)
Uncontrolled DM	–	1.6 (0.7)	1.9 (0.8)

HTN: Hypertension; DM: Diabetes Mellitus; SD: Standard Deviation; CI: Confidence Intervals.
[a] Hypertension controlled.
[b] Both hypertension and diabetes mellitus controlled.

130 mm Hg cannot be understated.[16] Poor quality of cardiovascular care by itself is a coronary risk factor in India.[17] The Prospective Urban Rural Epidemiologic (PURE) cohort study reported clear benefit of hypertension control in preventing cardiovascular disease and mortality but found treatment levels to be sub-optimal, especially in low-income countries.[18]

Table 3
Significant variables associated with control among patients with Hypertension only.

Variable	Category	Total $n = 2375$	Hypertension Controlled n (%)	Adjusted OR (95% CI)
Type of hospital	Private	911	215 (23.60)	1
	Public	1464	534 (36.48)	**1.96 (1.50–2.57)**
Presence of patient management software	No	2222	724 (32.58)	1
	Yes	153	25 (16.34)	**0.57 (0.34–0.93)**
No. of antihypertensive drugs	One	1500	535 (35.67)	1
	Two or more	651	131 (20.12)	**0.48 (0.38–0.60)**

Table 4
Prescription patterns flagged as potentially irrational.

	Hypertension only		Hypertension + Diabetes[a]	
	Controlled	**Uncontrolled**	**Controlled**	**Uncontrolled**
	***n* = 749**	***n* = 1626**	***n* = 183**	***n* = 896**
Prescription details	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Beta-blocker monotherapy	84 (11.2)	185 (11.4)	26 (14.2)	103 (11.5)
Any monotherapy other than RASI in presence of DM	–	–	91 (49.7)	367 (41.0)
No RASI when DM present	–	–	65 (35.5)	403 (45.0)
Dual RAS blockade (ACEI + ARB/2ARBs)	0 (0.0)	46 (2.8)	0 (0.0)	17 (1.9)
Frusemide monotherapy	0 (0.0)	2 (0.1)	2 (1.1)	2 (0.2)
Thiazides alone or in combination with beta-blockers	–	–	10 (5.5%)	54 (6.0%)
Totals	**84 (11.2)**	**233 (14.3)**	**101 (55.2)**	**439 (49.0)**

RAS: Renin Angiotensin System; ACEI: Angiotensin Converting Enzyme Inhibitor; ARB: Angiotensin Receptor Blocker; RASI: Renin Angiotensin System Inhibitor.
[a] Column totals are not 100% as rows do not represent mutually exclusive groups.

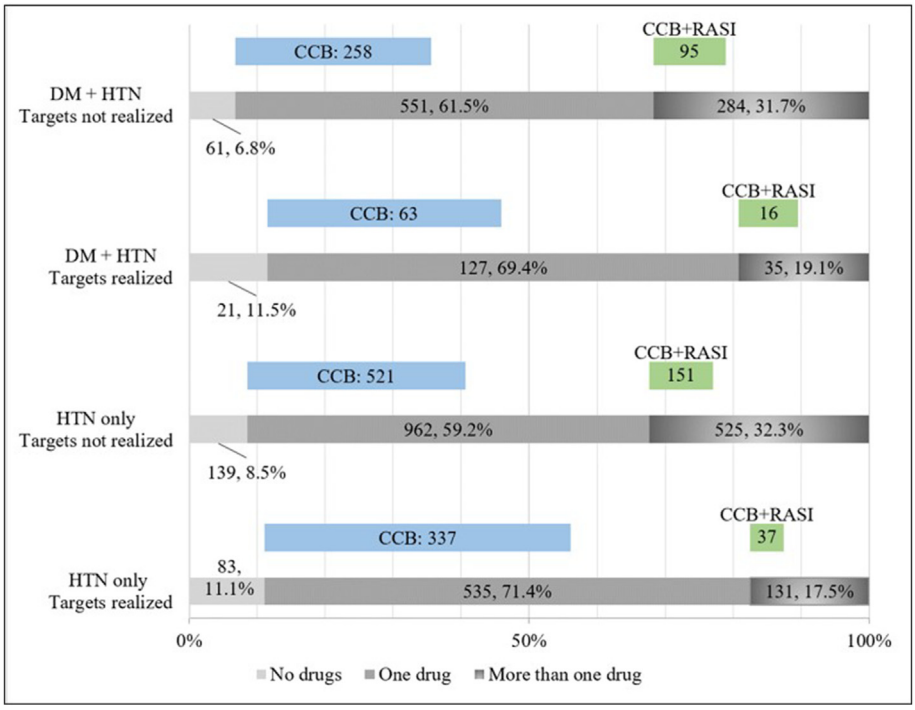

Fig. 1. Prescription pattern in hypertension – for each patient group, lower bars represent number of drugs and upper bars represent commonest drug/combinations
Abbreviations- HTN: Hypertension; DM: Diabetes Mellitus; CCB: Calcium Channel Blocker; RASI: Renin Angiotensin System Inhibitor.

4.1. Poor hypertension control levels

Hypertension control in Kerala was better than that reported in Guinea (16.3% among treated),[19] but lower than reports from South Korea (70.8% among those aware of their hypertension).[20] Studies from Switzerland and the United States of America reported a control level of 48% among those treated.[21,22] Similar to our study, diabetic hypertensives had poorer BP control levels in a study from Bangladesh (32.7% as against 46.0%).[23] But a study from China reported low hypertension control levels in both diabetics (19.0%) and non-diabetics (20.1%).[24] Hypertension control in Kerala seems better than that in urban India reported in a meta-analysis by

Anchala et al[25] (20.2%) and comparable to a recent NCD programme evaluation report in Kerala. (38.1%.)[26]

4.2. Factors associated with hypertension control

Prescriptions from public institutions indicated better BP control, possibly due to continued efforts of free drugs through health centres with lesser interruptions, and regular training[27] for which the state Health Department had won the United Nations Inter-Agency Task Force on the Prevention and Control of NCDs-2020.[28] Some findings were contrary to our expectations. Hypertension control was lower in institutions with quality certifications or when prescription generating software were used. Such institutions possibly have better specialist services or laboratories and may consequently cater to patients with more complicated disease. Polytherapy consistently indicated lower control levels for both conditions. Presumably, lower control levels would prompt practitioners to scale up the number of medications.

4.3. Rationality prescriptions and treatment intensification

Pharmacological management of hypertension seems to be a complex issue riddled by problems of potentially irrational prescriptions. Betablockers are not recommended as first-line agents for hypertension management, particularly in hypertension with diabetes. RASI may be more beneficial and nephroprotective in diabetic patients with hypertension than Calcium channel blocker (CCB) monotherapy.[29] Many patients with hypertension and diabetes were not receiving RASI and reasons for this needs to be explored further. Dual blockade of the RAS is also questionable.[30] Frusemide is also not the first choice antihypertensive in normal renal function due to its short action and rebound due to the RAS. Statin prescription practices also need further study. Even when there is no cardiovascular disease, statin treatment helps reduce cardiovascular mortality and morbidity.[31] Several studies have reported on possibility of inertia for therapeutic intensification in NCDs.[32,33] Studies have reported on physicians' dilemma in intensification in apparently healthy individuals[4] or fears of affecting the patient's delicate life balance.[34]

4.4. Limitations

An important limitation of our study is data quality due to incomplete information on many variables in the prescriptions – gender, socioeconomic status, body mass index, details on comorbidities, and whether the prescription featured a step-up or step-down of drugs. The prescription quality was generally modest. Still, the number of prescriptions studied added some value to the analysis. Also, doctors who consented to participate were aware that their prescriptions would be reviewed, but still we could include only about half of the prescriptions we collected, indicating the limitation of prescription-based studies.

4.5. Recommendations

Pharmacological management to achieve targets of hypertension and diabetes is critical for addressing the burden of NCDs. We find an immediate need for a system for standardized hypertension management at the peripheral level as recommended by Satish et al, adapted to the local context.[35] Doctors should be updated on latest hypertension treatment guidelines. Nursing staff can help documenting anthropometry and comorbidities. Digitisation of prescriptions may help improve their quality. These activities can be embedded within broader cardiovascular prevention interventions.[36,37]

This was one of the first such studies from Kerala reporting the provider and institutional factors of the NCD control based on prescriptions. Prescription-based studies may have some advantage over primary data collection from patients but prescription quality needs much improvement for it to be a tool for research or programme evaluation.

5. Conclusion

Through our cross-sectional study on prescriptions for hypertensive and diabetic patients in Kerala, we found a third of patients having control of the condition if it existed in isolation and a fifth of patients having control levels of both conditions when they co-existed. Several lacunae were also found in prescriptions of antihypertensive drugs, particularly low proportion of Renin Angiotensin System Inhibitor prescriptions when diabetes was present. Kerala is in more advanced epidemiological transition than the rest of India and poor control of hypertension and diabetes does not auger well for population health in the state. There is an immediate need for provider focused interventions to improve rational prescriptions and treatment intensification for achieving guideline recommended targets of hypertension and diabetes in the state.

What is Already Known?

- Provider and institutional level factors may influence control of risk factors like hypertension and diabetes that affect coronary health outcomes.

What this Study Adds?

- Prescription based studies may be useful in assessing hypertension control in population.
- Majority of persons with hypertension, with or without diabetes, do not have guideline-based blood pressure control levels, warranting further studies on rationality of prescriptions and possible hesitancy for treatment intensification.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ihj.2022.05.005.

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