Switching of antihypertensive drugs at Tertiary Care Government Hospital, Hyderabad, India: A cross-sectional retrospective investigation

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Abstract:
OBJECTIVE: Switching of antihypertensive drugs is attributed to uncontrolled blood pressure (BP) which imposes a great burden on health economics. But again, switching leads to accomplishment of the goal BP, thereby improving the health status. Such studies are well documented in developed nations but rarely reported in developing countries, especially in India. Therefore, the aim of this study was to evaluate various factors associated with switching of antihypertensive drugs.

METHODS: A cross-sectional retrospective investigation was performed using a standardized schedule adapting the World Health Organization indicators for drug utilization in a tertiary care government hospital, Hyderabad, India. A total of 429 prescriptions were monitored for a switchover to a different antihypertensive drug in 180 days.

RESULTS: The results revealed that the duration of hypertension (HTN) >5–10 years (adjusted odds ratio [aOR] = 3.73, \( P < 0.05 \)), two or more symptoms of HTN (aOR = 3.42, \( P < 0.05 \)), 2014 prescriptions (aOR = 4.54, \( P < 0.001 \)), polytherapy (aOR = 2.85, \( P < 0.001 \)), noncompliance to National List of Essential Medicine (NLEM) (aOR = 1.631, \( P < 0.05 \)), and systolic BP (SBP) (aOR = 1.77, \( P < 0.05 \)) were the predictors, which were highly likely to switch (38.5%) the antihypertensive drugs. Diuretics (0.7%) were poorly prescribed, the first line of therapy suggested by Seventh Joint National Committee (JNC VII). Stepwise logistic regression analysis revealed, the calendar year 2014 (odds ratio [OR] = 3.23, \( P < 0.001 \)), polytherapy (OR = 2.5, \( P < 0.001 \)), and the level of SBP ≥140 mmHg (OR = 1.82, \( P < 0.01 \)) as the three major predictors which showed a likelihood of switching medication.

CONCLUSIONS: Findings of the study reveals predictors of the switchover like uncontrolled SBP, duration of HTN, compliance with the list of NLEM drugs, polytherapy, enabling the clinicians to critically analyze the patients' profile, and hence, reach target BP soon, i.e., decreased cardiovascular risk.

Keywords: Antihypertensive drugs, India, retrospective study, switchover

Introduction

In India, the overall prevalence of raised blood pressure (BP) in adults has been continuously on the rise.¹ The global scenario also suggests the same.² Data from NHANES 2007–10 world over revealed that among those with high BP, 81.5% were aware of the condition, 74.9% were on treatment, however, only 52.5% have it controlled, and 47.5% of the peoples’ BP was inadequately controlled. While in India, 25.1% rural and 41.9% urban Indians were aware of their hypertensive status.³,⁴ The pooled estimate for the percentage of treated among those diagnosed with

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hypertension (HTN) in rural and urban areas was 24.9% and 37.6%, respectively. It is alarming that only 10.7% of rural and 20.2% of urban Indian hypertensive population have their BP under control.[14] In a study by Ambrosioni et al., inadequate BP control and side effects of the antihypertensive therapy were reported to cause a 66% discontinuation of treatment or switching to another drug.[9] Although switching medication because of adverse drug effects was less frequent than reported a decade ago. Similarly, a study in the Czech Republic showed that the major reason for switching antihypertensive treatment in general practice was insufficient BP control.[6]

The uncontrolled BP is the most important cardiovascular disease (CVD) risk factor which leads to switching of drugs.[7] And thereby, ushers to substantial expenditure on the health-care needs of the population. Worldwide, the projected direct and indirect cost of high BP in 2009 was $51.0 billion.[8] Hughes and McGuire reported an estimated total cost of HTN of 76.5 million pound sterling per annum, of which 26.9 million pound sterling was attributed to patients who switched or discontinued therapy.[9] It is noted that in India, limited data are available on the switching of antihypertensive drugs. Therefore, a retrospective cross-sectional hospital-based study was designed. The objective of the study was to evaluate the switching pattern of antihypertensive drugs and the associated factors in a tertiary care hospital, Hyderabad, India.

**Methods**

**Ethics approval**

A retrospective, cross-sectional hospital-based study was initiated after obtaining approval from Institutional Ethics Committee at National Institute of Nutrition (NIN) protocol number-02/2011/IV bearing ERC no. ECR/351/Inst/AP/2013 and the study center, Gandhi Hospital (Rc. No. IEC/GMC/2012/dt 18/6 bearing ERC no. ECR/180/Inst/AP/2013). Participants’ data were encoded by numbering, ensuring anonymity of the included subjects. Written informed consent was obtained from all participants.

**Source and data collection**

A schedule for monitoring the switching profile of antihypertensive drugs was indigenized, pretested, and standardized by following the World Health Organization (WHO) guidelines.[9] The study was carried out in the outpatient block in the Department of General Medicine at Gandhi Hospital during June–December 2012 and July–December 2014. As the HTN management guidelines were updated in the year 2013 (Indian HTN Guidelines III and JNC VIII), the switching profiles were studied in two calendar years, namely, 2012 and 2014 to note the variations if any.

The information was collected from the prescriptions of the patients attending the outpatient block after a thorough consultation with the physician. In this tertiary care hospital, each day a unit with an assigned set of clinicians examined the patients. Our study data were collected in a standardized schedule on every alternate day. It encompasses information regarding the sociodemographic details, symptoms relevant to HTN (headache, nausea, giddiness, palpitations, undefined pains, restlessness, stress, weakness, edema, and shortness of breath), antihypertensive drugs prescribed, number of comorbidities, and the total number of drugs prescribed.[10] The prescription was analyzed for the usage of generic names. The compliance to antihypertensives of the National List of Essential Medicine (NLEM) 2011 was also evaluated.[11] Different comorbidities such as diabetes, thyroid disorder, impaired glucose tolerance, dyslipidemia, asthma, chronic lung disorders, CVD, stroke, and renal impairment were recorded. Antihypertensive therapy could be monotherapy or polytherapy where a single-active ingredient is used or may have a single pill or multiple combinations of active antihypertensive ingredients respectively.

**Definition of cohort**

The data were captured from patients of age >25 years, of either gender who were chronic or de novo hypertensive and agreed to provide the information requested. On each clinic visit, patients’ BP was measured by the clinician once and if found elevated, it is repeated after at least 5 min of rest, where the second reading was usually used as the clinic BP. From JNC VII guidelines, the diagnosis of HTN was established by attending physicians if the patient had at least three separate readings of BP >140/90 mmHg in different visits.[12]

**Definition of switching therapy**

Switching of therapy is defined as the absence of a refill prescription in all subsequent clinic visits combined with the prescription of another antihypertensive drug of a different class within 180 days since the date of the first prescription.[13,14]

**Covariables and statistical analysis**

Descriptive statistics were used to understand the basic characteristics of the study population. The primary outcome measured was the switching profile of antihypertensive therapy within 180 days from the date of a prescription using the Chi-square test of heterogeneity. The various independent factors such as age, gender, classes of drugs, controlled systolic BP (SBP) and Diastolic BP (DBP), changes in SBP and DBP, calendar year, and other drugs prescribed were studied by applying binary logistic regression analysis, this being the secondary outcome. These predictors were
included to explore their possible role in switching of antihypertensive drugs as they are known to influence BP directly or indirectly. In addition, the adjusted odds ratio (aOR) was calculated considering dependent variable as change in therapy after controlling for the calendar year, age group, gender, duration of HTN, no. of symptoms, use of generic drug names, NLEM antihypertensive drugs, level of SBP and DBP, change in SBP and DBP, number of comorbid factors, and total number of drugs in the prescription variables using Logistic regression. Stepwise logistic regression was also applied to bring out the major factors influencing the switching of antihypertensive therapy. Nearly 95% confidence intervals along with P value were calculated.

The Statistical Package for Social Sciences (IBM SPSS Statistics, NY, USA) version 16.0 was used for all statistical analyses. All P < 0.05 were regarded as statistically significant.

**Results**

A total of 652 hypertensive individuals were initially screened. Of these, 58 patients were treated with other classes of antihypertensive agents (α-blockers, vasodilators, and other classes of antihypertensive) were not included in the study due to their fewer numbers along with 44 patients who were uncooperative and noncompliant. We were left with 550 prescriptions, among these only the prescriptions with complete data were evaluated for the switching study; finally, 429 hypertensive cases were considered in the study.

In this study, males were 311 (72.5%) and 118 (27.5%) were female belonging to the different age groups [Table 1] due to gender disparity. Most of the hypertensives (64.9%) were <60 years of age, suggesting that the higher proportion of study population was not having age-related HTN. The mean age ± standard error of the total population was found to be 51.8 ± 0.56. The duration of HTN is defined as the time period from the date of the first diagnosis of HTN till present date. A majority of the patients were in the <1-year group (70.2%) of the duration of HTN. It indicates a rather drug-naïve group of the population suffering from HTN followed by 1–5-year group (22.8%) of the duration of HTN. It is seen that the majority of the study population had only essential HTN (86.5%) and few (13.5%) comprised other comorbidities. Most of the patients were almost similar in carrying any one symptom of HTN (43.4%) whereas only 5.4% had two or more symptoms and 51.3% were devoid of any symptoms associated with HTN. It was seen that as meager as 0.7% prescriptions contained thiazide diuretics. Among all antihypertensive drug visits, initially, calcium channel blockers (CCBs) (20.3%) and Beta-blockers (BBs) (17.5%) were the most commonly prescribed drugs, followed by angiotensin-converting enzyme inhibitors (ACEIs) (15.6%), angiotensin-receptor blockers (ARBs) (15.2%), and combination therapy (30.5%). Monotherapy (69.5%) was highly preferred. The prescriptions analyzed for the usage of generic names had 80.7% prescriptions with generic names while 17% encompassed trade names, and 2.3% had both the generic and trade names. Most of the patients (69.2%) were prescribed antihypertensive drugs in accordance with the NLEM. Almost similar numbers of people were able to reach (52.4%) and not reach goal SBP (47.6%) whereas large number (60.8%) were unable to control DBP. The total number of drugs was also captured, it revealed the prescription of two drugs (36.8%) were the highest.

In this heuristic study, it was observed that 38.5% of the prescriptions hosted drug switching. In relation to this, the various factors captured in the schedule were studied to understand which of these have contributed significantly to antihypertensive drug switching [Table 1]. The data analysis showed significant higher switching in the year 2014, males, patients with uncontrolled SBP and relatively greater uncomplicated hypertensives, i.e., no comorbidity. In case of drugs prescribed, BBs, CCBs, ACEIs, and ARBs were significantly less in drug switchers. In addition, lesser prescriptions with monotherapy were associated with switchers, and greater prescriptions in compliance to NLEM were associated with nonswitchers.

Drug switching, the outcome variable was measured using binary logistic regression analysis [Table 2]. Among the predictors which had shown a significant association with drug switching, the males who were significantly highly likely (odds ratio [OR] =1.7, P = 0.022) and hypertensives with concomitant comorbidities (OR = 0.51, P = 0.036) who were unlikely to switch drugs did not show the same when aOR (males; aOR = 1.49, P > 0.05 and comorbidity; aOR = 0.72, P > 0.05) was calculated.

The calendar year 2014 (aOR = 4.54, P < 0.001), duration of HTN >5–10 years (aOR = 3.73, P < 0.05), two or more symptoms in relation to HTN (aOR = 3.42, P < 0.05), polytherapy (aOR = 2.85, P < 0.001), noncompliance to NLEM (aOR = 1.63, P < 0.05), uncontrolled SBP (aOR = 1.77, P < 0.05) were the predictors which were highly likely to switch the antihypertensive drugs. The OR could not be calculated for the antihypertensive drugs when diuretics were included owing to its less frequency (1.8%) in the switchers and no prescriptions in nonswitchers. Therefore, the analysis was conducted after excluding diuretics which revealed no significant associations with antihypertensive drug switching. Likewise, even aOR could not be generated.
Table 1: Characteristics of switchers versus nonswitchers

| Variable                        | Total (n=429), n (%) | Nonswitchers (n=264; 61.5), n (%) | Switchers (n=165; 38.5) |
|---------------------------------|----------------------|----------------------------------|-------------------------|
| Age (years)                     |                      |                                  |                         |
| <50/50-59                       | 168/122 (39.2/28.5)  | 104/79 (39.4/29.9)               | 64/43 (38.8/26.1)       |
| 60-69/≥70                       | 109/30 (25.4/7)      | 63/18 (23.9/6.8)                 | 46/12 (27.9/7.3)        |
| Gender*: Male/female            | 311/118 (72.5/27.5)  | 181/83 (68.6/31.4)               | 130/35 (78.8/21.2)      |
| Duration of hypertension (years) |                      |                                  |                         |
| <1/1-5                          | 301/98 (70.2/22.8)   | 184/62 (69.7/23.5)               | 117/36 (70.9/21.8)      |
| >5-10                          | 22/8 (5.1/1.9)       | 13/5 (4.9/1.9)                   | 9/3 (5.5/1.8)           |
| Number of symptoms: 0/1/≥2      | 220/186/23 (51.3/43.4/5.4) | 141/111/12 (53.4/42.4/5.5) | 79/75/11 (47.9/45.5/6.7) |
| Drug class*                     |                      |                                  |                         |
| Diuretic                        | 3 (0.7)              | 0 (0)                            | 3 (1.8)                 |
| BB/CCB                          | 75/87 (17.5/20.3)    | 50/62 (18.9/23.5)                | 25/25 (15.2/15.2)       |
| ARB/ACEI                        | 65/67 (15.2/15.6)    | 42/41 (15.9/15.5)                | 23/26 (13.9/15.8)       |
| Diurety/thritherapy             | 112/20 (26.1/4.7)    | 58/11 (22.4/2)                   | 54/9 (32.7/5.5)         |
| Generic name usage: Yes/no/both | 73/346/10 (17.8/72.3) | 48/207/9 (18.2/78.4/3.4) | 25/139/1 (15.2/84.2/0.6) |
| Type of therapy*: Monotherapy/polytherapy | 298/131 (69.5/30.5) | 195/69 (73.9/26.1) | 103/62 (62.4/37.6) |
| NLEM compliance*: Yes/no        | 297/132 (69.2/30.8)  | 193/71 (73.1/26.9)               | 104/61 (63/37)          |
| Control SBP*: <140/≥140         | 225/204 (52.4/47.6)  | 151/113 (57.2/42.8)              | 74/91 (44.8/55.2)       |
| Control DBP: <90/≥90            | 168/261 (39.2/60.8)  | 107/157 (40.5/59.5)              | 61/104 (37/63)          |
| Change in SBP: Decrease/increase/constant | 301/750 (70.2/18.2/11.7) | 182/46/36 (68.9/17.9/13.6) | 119/32/14 (72.1/19.4/8.5) |
| Change in DBP: Decrease/increase/constant | 229/89/111 (53.4/20.7/25.9) | 140/54/70 (53/20.5/26.5) | 89/35/41 (59.2/12.24.8) |
| Comorbidity*: 0/≥1              | 371/58 (86.5/13.5)   | 221/43 (83.7/16.3)               | 150/15 (90.9/9.1)       |
| Total number of drugs           |                      |                                  |                         |
| 1/2/3                           | 33/158/117 (7.7/36.8/27.3) | 23/88/75 (8.7/33.3/28.4) | 10/70/42 (6.1/42.4/25.5) |
| 4/5 or more                     | 76/45 (17.7/10.5)    | 44/34 (16.7/12.9)                | 32/11 (19.4/8.7)        |
| Calendar year*: 2012/2014       | 157/272 (36.6/63.4)  | 114/150 (43.2/56.8)              | 43/122 (36.6/63.4)      |

*P < 0.05, ***P < 0.001. Dithery and thritherapy are defined as prescriptions with two and three active antihypertensive ingredients, respectively. Polytherapy refers to the prescription of a single pill or multiple pills consisting of two or more than two active antihypertensive ingredients. All percentages are across columns. A Chi-square tests of heterogeneity are performed comparing the respective proportions across rows. "/" separates variables and numerical data in the table.

ACEI=Angiotensin-converting enzyme inhibitor, ARB=Angiotensin-receptor blocker, CCB=Calcium channel blocker, BB=Beta blocker, NLEM=National list of essential medicines, SBP=Systolic blood pressure, DBP=Diastolic blood pressure

Finally, stepwise logistic regression analysis suggested the calendar year 2014 (OR = 3.23, P < 0.001), polytherapy (OR = 2.5, P < 0.001), and the level of SBP ≥140 mmHg (OR = 1.82, P < 0.001), were the major predictors that showed a likelihood of antihypertensive drug switching in the cross-sectional study.

**Discussion**

Our study recorded a switching rate of 38.5% whereas a study from the United States exhibited exorbitant 59.9%–74.9% switching. Another study conducted in Italy based on the patient questionnaire observed a 52.4% switching, after which Taiwan witnessed around 29% switching. Some studies from the European nations such as Italy, Dutch, and Sweden have shown around 15% or more. On the other hand, studies from China disclosed very less switchover (5.7% and 3.9%) of antihypertensive medication change by the clinicians. Our study recorded a switching rate of 38.5% whereas a study from the United States exhibited exorbitant 59.9%–74.9% switching. Another study conducted in Italy based on the patient questionnaire observed a 52.4% switching, after which Taiwan witnessed around 29% switching. Some studies from the European nations such as Italy, Dutch, and Sweden have shown around 15% or more. On the other hand, studies from China disclosed very less switchover (5.7% and 3.9%) of antihypertensive medication change by the clinicians. However, polytherapy could be a single pill combination or multiple pill combination which was not differentiated.

The updated HTN guidelines both on the National (Indian HTN Guidelines III) and International (JNC VIII) front have perhaps made an impact on the switching profile as in the calendar year 2014; more switching was observed as compared to the 2012 year prescriptions. Physicians cautiously examined the patient profile and made the change in the drug regimen accordingly. Therefore, with more number of symptoms presented by the patients, the clinicians carefully prescribed a different suitable antihypertensive medication leading to a significant drug switching, hence, associated with two or more symptoms.

In the number of antihypertensive medications prescribed, monotherapy (69.5%) was predominantly seen. Unlike the study conducted in the Chinese population, where combination therapy (single pill combination) showed less likelihood of drug switching, our study showed that the polytherapy was significantly associated with a change in the medication. However, polytherapy could be a single pill combination or multiple pill combination which was not differentiated.
in our study; this multiple pill combination could have led to antihypertensive medicine switchover as >1 drug/multiple pill combination used for treating HTN may prime to inefficient BP control due to less adherence.\cite{21} In addition, it was also seen that increasing the number of pills had a negative effect on compliance and on persistence on therapy, translating into poor clinical outcomes.\cite{21,22}

NLEMs are made with consideration to disease prevalence, efficacy, safety, and comparative cost-effectiveness of the medicines. Such medicines are intended to be available in adequate amounts, in appropriate dosage forms and strengths with assured quality. They should be available in such a way that an individual or community can afford.\cite{11} Since the list aid in affordability and accessibility of medicines needed to satisfy the priority health-care needs of the population, when NLEM is not abided by, there is a trend showing switching of antihypertensive drugs. A Brazilian study has shown an adherence of 76.8% with Brazilian NLEMs (RENAME), and 63% on the WHO list.\cite{23} An Indian study reported compliance with NLEM (71.7%) in relation to antihypertensive medication which is one of the core drug use indicators of WHO rationale drug use.\cite{24} It is important to note that hardly any studies have reported compliance with NLEM as one of the factors affecting switching of antihypertensive therapy.

The Western population has shown that “failure to achieve Goal BP” as the most commonly noted reason for a change in antihypertensive therapy at about 67.6%–74.3%.\cite{15} Likewise, Nationwide Czech Republic study revealed that uncontrolled SBP and DBP (89.6% and 81.5%, respectively) contributed to switching medication.\cite{6} In our study, a 55.2% of the population who switched drugs were unable to control their SBP, and a higher proportion of the switchers failed to control DBP when compared to the nonswitchers (63% vs. 59.5%, \( P > 0.05 \) though significantly not different. In contrary, the study conducted in Western country demonstrated higher initial DBP association with a higher likelihood of having “failure to achieve goal BP” as the reason for the change in the medical records whereas SBP was not statistically significant.\cite{15}

### Table 2: Factors associated with antihypertensive switching within 180 days from the first date of prescription

| Variable                       | Switchers |               |               |               |               |
|-------------------------------|-----------|---------------|---------------|---------------|---------------|
|                               | n (%)     | Crude OR      | Adjusted OR\(^a\) | Adjusted OR\(^b\) |               |
| Female                        | 35 (21.2) | 1 (reference) | 1 (reference)  |               |               |
| Male                          | 130 (78.8)| 1.7 (1.08-2.68)* | 1.49 (0.88-2.51) |               |               |
| Duration of hypertension (years) |          |               |               |               |               |
| <1                            | 117 (70.9)| 1 (reference) | 1 (reference)  |               |               |
| 1-5                           | 36 (21.8) | 0.91 (0.57-1.46) | 1.78 (0.936-3.385) |               |               |
| >5-10                         | 9 (5.5)   | 1.09 (0.45-2.63) | 3.73 (1.2-11.59)* |               |               |
| >10                           | 3 (1.8)   | 0.94 (0.22-4.02) | 2.91 (0.58-14.59) |               |               |
| Number of symptoms            |           |               |               |               |               |
| 0                             | 79 (47.9) | 1 (reference) | 1 (reference)  |               |               |
| 1                             | 75 (45.5) | 0.82 (0.55-1.23) | 1.18 (0.76-1.85) |               |               |
| ≥2                            | 11 (6.7)  | 0.61 (0.26-1.45)* | 3.42 (1.2-9.73)* |               |               |
| Type of therapy               |           |               |               |               |               |
| Monotherapy                   | 103 (62.4)| 1 (reference) | 1 (reference)  |               |               |
| Polytherapy                   | 62 (37.6) | 1.7 (1.12-2.58)* | 2.85 (1.69-4.8)*** | 2.5 (1.56-4.0)*** |               |
| NLEM compliance               |           |               |               |               |               |
| Yes                           | 104 (63)  | 1 (reference) | 1 (reference)  |               |               |
| No                            | 61 (37)   | 1.594 (1.05-2.42)* | 1.63 (1.00-2.65)* |               |               |
| Control SBP                   |           |               |               |               |               |
| <140                          | 74 (44.8) | 1 (reference) | 1 (reference)  |               |               |
| ≥140                          | 91 (55.2) | 1.64 (1.11-2.43)* | 1.77 (1.07-2.94)* | 1.82 (1.21-2.76)** |               |
| Comorbidity                   |           |               |               |               |               |
| 0                             | 150 (90.9)| 1 (reference) | 1 (reference)  |               |               |
| 1 or more                     | 15 (9.1)  | 0.51 (0.28-0.96)* | 0.72 (0.33-1.59) |               |               |
| Calendar year                 |           |               |               |               |               |
| 2012                          | 43 (36.6) | 1 (reference) | 1 (reference)  |               |               |
| 2014                          | 122 (63.4)| 2.16 (1.41-3.3)*** | 4.54 (2.06-10.0)*** | 3.23 (2.0-5.22)*** |               |

\(^a\)Adjusted OR calculated after controlling for all the variables in the table except for drug class. \(^b\)Adjusted OR from stepwise logistic regression analysis of switchers versus nonswitcher. Polytherapy refers to the prescription of a single pill or multiple pills consisting of two or more than two active antihypertensive ingredients. All percentages are across columns. NLEM=National list of essential medicines, SBP=Systolic blood pressure, OR=Odds ratio
Conclusion

In summary, this study unveils important factors associated with switching of antihypertensive drugs such as the prescriptions of the calendar year 2014, duration of HTN >5–10 years and a number of antihypertensive drugs prescribed, which may be multidrug pill combination and noncompliance to NLEM along with the uncontrolled level of SBP. The information generated in the current study will facilitate physician for rationalizing the prescriptions. The directions for the future studies should include determining the essential factors such as the drug adherence and compliance, fixed drug combinations, adverse effects, and reasons for switching. These variables will give a comprehensive understanding of the switching of antihypertensive drugs.

Study strengths and limitations

The majority of the study participants have no concomitant comorbidities, and the findings are therefore only applicable to a relatively healthy and drug-naive population. In addition, we captured the patterns of antihypertensive utilization over a relatively short study period. Second, the study center being a tertiary care government hospital represents only lower and middle-income groups whereas patients from the higher income group could not be studied.

It is pertinent to mention that the accuracy of data collection is high as it was collected after pretesting the schedule by a trained and skilled individual in the presence of a physician. Furthermore, as there is a dearth of studies on switching of antihypertensive drugs in the Indian context, this study will facilitate in aiding the clinicians to understand the various factors involved in switching of antihypertensive drugs and make a rationale drug choice.

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Conflicts of interest

There are no conflicts of interest.

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