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Assessing the Ayurvedic prescribing trends on the basis of WHO drug use indicators



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ABSTRACT

Background: Ayurvedic prescriptions are often challenged for their rationality. Excessive use of proprietary medicines, *rasa* preparations, and *samshodhana* without any justification and deliverable benefits outweighing the other forms of safer, cheaper and less time consuming therapies is putting the Ayurvedic prescribing trends into question. In Ayurvedic practice, prescriptions are often individualized with substantial variability between the choices of drugs. Although being welcomed as an advanced approach of prescription writing by making it tailor made, this method also allows for lapses to creep in thus making it necessary to check common trends of prescribing in Ayurveda and to see whether it raises any caution.

Objectives: The objective of this study was to create a check for common trends of prescribing in Ayurveda and to see if such checks raise any caution.

Materials and methods: Present study utilizes the WHO drug use indicators as a preliminary tool for analyzing Ayurvedic prescriptions.

Results: It was found that with a small modification, this tool can help immensely in screening of Ayurvedic prescriptions.

Conclusion: Based on the results obtained through this study, it can be concluded that the WHO drug use indicators, with a small modification, can help in identifying the prescribing trends in Ayurveda and can also help in suggesting remedial measures in case certain anomalies are found.

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1. Introduction

Rational use of drugs has been a concern worldwide [1]. There are reports of misuse, over use and inappropriate use of drugs occurring consistently and globally. A few classes of drugs are widely known for their over and irrational use through prescriptions to the extent that the phenomenon may be called as 'prescribing abuse'. Irrational combination of drugs expose the people to pharmacologically active molecules which are often undesired, but are forced to be taken as they are combined with something which is desired. This freebie in a medical prescription may have its own merits and demerits. The concept of polypills although has given a rational face to the debate by viewing that a judicial combination of all that which is essentially prescribed in a given set of morbidities may have its practical values. The common example is the cardiovascular

morbidity where a low dose aspirin, a hypolipidemic agent and an antihypertensive are often co-prescribed [2].

We are aware that an inadvertent use of antibiotics through prescription has reached to the state of havoc in developing countries. The irrationality here is mainly associated with need, choice, dose and duration of the antibiotic therapy. A poly-pharmacy (some times called cocktail therapy) is a newer trend in practice where many antibiotics are given for a single problem on the pretext of covering a wide range of pathogens and so to treat a disease by using all the weapons available in store.

What if you are prescribed a medicine which was not totally undesired for your state of health? This may have implications more than we can presume. Besides taxing your pocket, this will expose you to something totally undesired without having a slightest idea that how your body is going to react to it. This is alarming with antibiotic use as with every such exposure, we render our immune system weaker and pathogens stronger. Eventually, after repeated practice of irrational use of antibiotics, we will land at a stage where we see that the simple antibiotics are

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no more effective and hence more complex, newer molecules of antibiotics are needed to treat the conditions which have been curable with most simple antibiotics erstwhile.

Antibiotic resistance is the ugliest outcome of its irrational use and for conditions like tuberculosis it came up as a real threat difficult to deal with. Each year, in the United States alone, at least 2 million people get infected with bacteria that are resistant to antibiotics and 23,000 people die as an outcome of these infections [3]. Including Europe, this death toll rises up to 50,000 a year. It is estimated that antibiotic resistance may cause 10 million deaths a year by 2050 if the current trend of antibiotic misuse continues [4]. Not to surprise, this toll is going to be the highest among all causes of death and will be higher than the deaths caused by cancer which is supposed to be the 2nd largest cause of death by 2050. These deaths cumulatively will cost 2–3.5% reduction in Gross Domestic Product (GDP) equating up to 100 trillion USD. Drug abuse in the form of prescription medicine and OTC medicines is the other side of the picture which adds to the total sinisterity [5].

Besides antibiotics, there are many other drugs which have been noticed for prescribing abuse. Anxiolytics, hematinics, antioxidants, proton pump inhibitors, pre and probiotics and various health supplements including the compounds containing vitamins, minerals and calcium are the drugs which are often over prescribed without thinking about their actual need in a prescription. As a consequence, surprisingly bizarre combinations of health supplements are available in the market on the prelude to be prescribed to patients by the prescribers. One example to this phenomenon is a significant increase in anxiolytic drug prescriptions in past few years; in particular to younger age group [6].

Seeing the alarming increase in irrational prescription writing and its perceived threat in terms of morbidities and economic burden, a movement was started to catch the trends and to bring back the rationality in prescription writing. WHO took the lead initiative in this regard. The first conference on the issue was organized at Nairobi in 1985 on Rational Use of Drugs [7]. Since then, the past three decades have witnessed a huge sum of work upon rationalization of medical prescriptions. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards [8]. Rational drug use is simply defined as “medications appropriate to the clinical needs of the patients, in doses appropriate to their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community”. This is important to observe that choosing a high cost intervention compared to a low cost yet equally effective alternative also constitute irrational practice.

To identify the drug use trends in a given facility, it was important to develop certain tools as the indicators of drug use. As an irrational use of drug may include use of too many medicines per patient (“poly-pharmacy”); inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimens, it is obvious to think that the drug use indicators should be able to identify such trends of practice dependably so that an effective measure may subsequently be taken up.

A few core drug use indicators have been identified by the WHO as a dependable measure to identify these trends of practice and quality of patient care offered at individual facility. These indicators are mainly prescribing indicators, patient care indicators and facility indicators to give a comprehensive view of what is being done in terms of overall patient care.

Prescribing indicators mainly comprise of average number of drugs per encounter, percentage of drugs prescribed by generic names, percentage of encounters prescribed with an antibiotic, percentage of encounters prescribed with an injection, percentage of encounters prescribed with essential drug list (EDL). By identifying the trends on the basis of such indicators, it can easily be judged if the practice in a given facility is following the set standards or there are deviations required to be addressed.

It is observed that although, rationality of the prescriptions is an issue equally relevant to every health care system, little is done in other health care practices to see if they are following certain standards of practice. Ayurveda, a popular system of health care in India and South East Asia has a highly variable and individualized trend of prescribing. Little is done so far to crosscheck the rationality of such individualized prescriptions in Ayurveda on the basis of prescribing indicators. Ayurveda comprises of medicines composed of herbs, metals, minerals and animal products. Any component among this list, if irrationally prescribed, threatens the resources to be wasted for no gains and at the same time increases the cost of cure injudiciously. Rationality in an Ayurvedic prescription looks even more important when we see that such compounds are often composed of precious metals like gold and silver, herbs and plants which may be threatened for their survival and of animal products causing undesired sacrifice of endangered animal species for no real gains. Exposing the patient for all possibility of unforeseen hazards is an addition to all this.

It is therefore imperative to think that Ayurvedic prescriptions should also be brought under the purview of drug use studies in order to define the trends and to fix the rationality. Developing a new drug indicator for Ayurvedic drug usage should be an ideal approach to begin with. To identify the feasibility of such studies, a modification in the existing WHO core prescription indicators was proposed and adopted in this study as a preliminary initiative to look more seriously into the issue. The observations obtained in the study were alarming and were strongly recommended for more serious studies to look at the prescribing trends in Ayurveda.

2. Materials and methods

2.1. Setting of the study and sample selection

The study was conducted at State Ayurvedic College and Hospital, Lucknow. Indoor prescriptions from the hospital during year 2015 were considered as the population to be screened. A simple random selection of the prescriptions from the whole bulk of prescriptions for the concerned year was done to select the samples for evaluation.

2.2. Adapting the WHO drug use indicators as per Ayurveda requirements

WHO drug use indicators are designed to screen the pattern of allopathic drug prescribing and patterns of its usage. Utilizing the core concept of drug use indicator, a modification in the WHO drug use indicator to suit it to Ayurveda drug use pattern was attempted. A thorough peer discussion was attempted initially to identify the common components of Ayurvedic prescriptions. On the basis of such discussions, crucial components of Ayurvedic drug prescription were identified (Table 1).

To attempt the modifications in WHO drug use indicators to be used for Ayurveda, following definitions were adopted to render more clarity to various components of the study.

Table 1
Components of Ayurvedic prescription as a drug use indicator.

No.	Component of Ayurvedic prescription	Availability in WHO drug use indicator	Nearest component in WHO drug use indicator	Proposed advantage
1	Number of drugs in a single prescription	Yes	–	
2	Number of classical drugs in a single prescription	No	Use of generic drugs	Will help in identification of pattern of classical drug use in Ayurvedic prescriptions
3	Number of proprietary drugs in a single prescription	No		Will help in identification of pattern of proprietary drug use in Ayurvedic prescriptions
4	Number of <i>rasa</i> preparations in a single prescription	No	Use of Antibiotics	Will help in identification of pattern of <i>rasa</i> drug use in Ayurvedic prescriptions
5	Number of prescriptions containing procedures prescribed	No	Use of Injections	Will help in identification of pattern of <i>pancha karma</i> procedures recommended in Ayurvedic prescriptions
6	Ratio of drugs from EDL prescribed in prescriptions	Yes	Same	Will help in identifying the rationality of prescription on the basis of number of drugs prescribed from EDL

2.3. Classical Ayurvedic drugs

Drugs having a reference in some Ayurvedic classical text were considered classical Ayurvedic drugs. These drugs are prepared as per the methods and compositions described in Ayurvedic texts and are marketed with their original names (often followed by the name of the text in parenthesis from where the reference is taken). For the purpose of the study, these are also called as generic as these drugs are essentially marketed with same name and composition by all the pharmaceutical companies. These formulations are available in AFI. It should however be understood that using the word generic here is not in parallel to classical definition of generic drugs as is adopted in allopathy.

2.4. Proprietary Ayurvedic drugs

Proprietary drugs in Ayurveda are defined as compound formulations not described in classical Ayurvedic texts and are developed by pharmaceutical companies having a proprietary right on the drug formulation and its marketing. These formulations are not available in AFI.

2.5. Ayurvedic *rasa* drugs

Any prescribed drug having a suffix of *rasa* at the end of its name is considered a *rasa* drug for the purpose of the study. These are usually the herbo-metallic preparations often containing mercury as one essential component.

2.6. Procedures

Various bio-purificatory procedures (called as *pancha karma* procedures) recommended in the prescription are considered as procedures for the purpose of the study. These include a single or a set of multiple procedures recommended to the same patient in a single prescription. The *pancha karma* procedure includes procedures classified as *purva karma* (preparatory procedures), *Pradhana karma* (major procedures) and *Paschata karma* (post procedures).

2.7. EDL of Ayurveda

EDL of Ayurveda as recommended by the Ministry of AYUSH in year 2013 is considered EDL for the purpose of this study [9].

Instead of evaluating the use of generic drugs, antibiotics, and injections as per the WHO indicator list, classical Ayurvedic drugs, *rasa* drugs and procedures were evaluated in this study along with essential utilization of the same method as it is recommended in the WHO protocol.

2.8. Data collection

Data was collected on the basis of physical observation of each prescription included in the study for specified parameters. Data was initially collected on the performa specifically designed for the purpose of study and subsequently plotted on Microsoft Excel for the purpose of analysis. The data collection was done from March to May 2016.

2.9. Statistical analysis

Statistical analysis for each indicator was done on the basis of formula recommended in the WHO drug use indicator tool.

WHO prescribing indicators and the formula used to assess the rationality of the prescriptions are enlisted below [4]:

- Average number of drugs per prescription = total drugs prescribed/prescriptions used.
- Percentage of drugs prescribed by generic name = total generic drugs prescribed/total drugs prescribed $\times 100$.
- Percentage of prescriptions in which antibiotics were prescribed = prescriptions in which at least one antibiotic was prescribed/total prescriptions $\times 100$.
- Percentage of prescriptions in which an injection was prescribed = prescriptions in which at least one injection was prescribed/total prescriptions $\times 100$.
- Percentage of drugs prescribed included in the essential medicines list (EML) = total drugs prescribed included in the EML/total drugs prescribed $\times 100$.

The formulae adopted in this study after modifying the WHO prescribing indicator for Ayurveda are as follows:

- Average number of drugs per prescription = total drugs prescribed/prescriptions used.
- Percentage of classical drugs prescribed = total classical drugs prescribed/total drugs prescribed $\times 100$.
- Percentage of proprietary drugs prescribed = total proprietary drugs prescribed/total drugs prescribed $\times 100$.
- Percentage of *rasa aushadhi* prescribed = total *rasa aushadhi* prescribed/total drugs prescribed $\times 100$.
- Percentage of prescriptions in which *rasa aushadhi* were prescribed = prescriptions in which at least one *rasa aushadhi* was prescribed/total prescriptions $\times 100$.
- Percentage of prescriptions in which a procedure was prescribed = prescriptions in which at least one procedure was prescribed/total prescriptions $\times 100$.
- Percentage of drugs prescribed included in the EDL = total drugs prescribed included in the EDL/total drugs prescribed $\times 100$.

2.10. Ethical clearance

Study proposal was duly approved by the Departmental Research Committee and Institutional Ethics Committee of State Ayurvedic College and Hospital, Lucknow.

3. Results

In year 2015 total 1576 prescriptions were generated in the IP section of the concerned hospital. Among these, 1535 prescriptions were found to be generated by Ayurvedic physicians comprising the sample to be included in the study. 256 prescriptions (16.67%) were randomly chosen through simple random sampling method (every 6th prescription of the total was selected for screening) and were screened for the identified parameters. Among selected prescriptions 11 (4.29%) were found incomplete (having instruction for hospital admission only) and hence eliminated from the study. Rest 245 prescriptions were further screened for various WHO drug use indicators in view of their use for Ayurvedic prescription screening (Fig. 1; Table 2).

3.1. Average number of drugs per prescription

In 245 prescriptions screened for the study, average number of drug prescribed was found to be 6.14 per prescription. The minimum number of drugs prescribed was found to be 1 whereas the maximum number was found to be 16 among the screened prescriptions.

3.2. Prescribing ratio of classical drugs and proprietary drugs

The average ratio of classical drugs prescription among all drugs prescribed is found to be 79.68%. The proprietary drugs were found to be prescribed on an average of 20.32%. Approximate ratio of classical and proprietary drugs in screened prescriptions is 4:1.

3.3. Total number of prescriptions containing proprietary medicine

Among all screened prescriptions 140 (57.14%) prescriptions were found to contain proprietary medicines. Minimum number of such medicines in a prescription was 1 whereas the maximum

Table 2
Observations in the study.

Number	Parameter	Observation	%
1	Total number of prescriptions	1576	
2	Prescriptions generated by Ayurvedic physicians	1535	97.39
3	Number of prescriptions screened	256	16.67
4	Incomplete prescriptions	11	4.29
5	Number of prescriptions evaluated	245	95.70
6	Total number of drugs prescribed	1506	
7	Total number of classical drugs	1200	79.68
8	Total number of proprietary drugs	306	20.31
9	Total number of prescriptions containing proprietary drugs	140	57.14
10	Total prescriptions having <i>rasa aushadhi</i>	81	33.06
11	Total <i>rasa aushadhi</i> prescribed	94	6.24

number was 6. Average number of proprietary medicines prescribed in a prescription was 1.4.

3.4. Total number of *rasa aushadhi*

The *rasa aushadhi* prescription is found to be 6.24% of total drugs prescribed. Among all, 81 (33.06%) prescriptions were found containing *rasa* preparations. The maximum number of *rasa* drugs prescribed in a single prescription was 5 and the minimum was 1.

3.5. Total number of procedures prescribed

This information could not be sought as reliable information and was not available through the prescriptions.

3.6. Percentage of drugs prescribed from EDL

This information also could not be obtained as in the concerned hospital; the availability of the drugs in hospital dispensary was not as per the 2013 EDL.

4. Discussion

Any study pertaining to the pattern of drug prescribing in a health care setting may give valuable information about the type and the level of care being offered by individuals or the institutions.

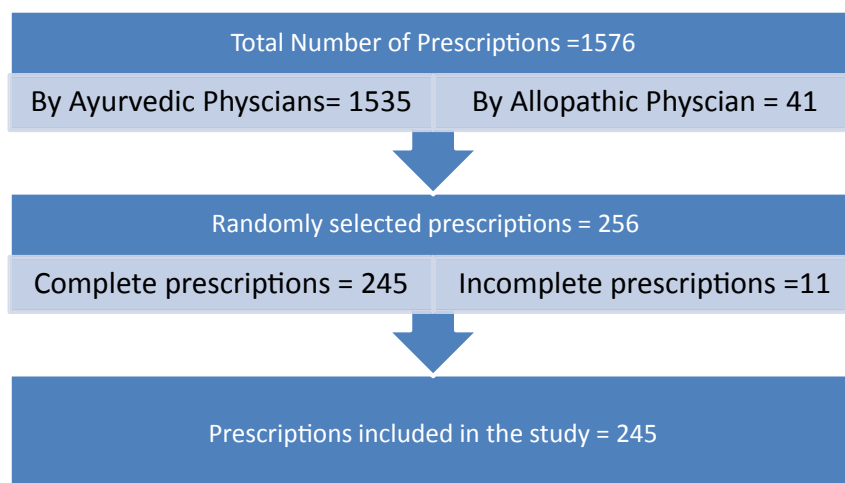


Fig. 1. Study flow chart.

This also gives information about the preference of prescribers between various choices of interventions and drugs. From Ayurvedic perspective, besides the others, this enquiry in addition, may give crucial information about pattern of *rasa aushadhi* use and the *pancha karma* procedure recommendations in the same enquiry.

Classical drugs in Ayurveda are the drugs having a reference in Ayurvedic classical texts, specified composition, method of formulation and indications based upon the Ayurvedic understanding of the cause of the disease and its treatments. Ayurvedic teaching institutions offer teaching to their students in the way that a disease pathogenesis may be inferred through Ayurvedic principles and various methods of interventions may judiciously be applied with an objective of pathology dissociation (*samprapti vighatan*). Classical formulations offer a possibility to be deciphered on the basis of Ayurvedic fundamentals for their proposed pharmacological actions. Classical formulations also offer a uniformity of their composition and therefore of their effects, irrespective of their manufacturing companies. If the manufacturing unit is trustworthy, this may be presumed that the action of the one formulation will remain at par with the product of any other company having a similar formulation. This offers a unique cost advantage to the patients for such products being competitively priced. This argument is somewhat similar to the one what is raised in favor of generic drugs in allopathy in contrast to the branded drugs promoted by brand names.

Proprietary drugs, on the other hand are having their own advantages and disadvantages. Although, proprietary drugs may be the outcome of the R & D of some pharmaceutical company or may be the result of a clinical trial of some empirical formula, justifying their promotion, it also proposes a monopoly on the combination and its marketing. It is for this reason, such products are often irrationally priced compared to the classical formulations with much similar composition [10]. Sometimes, there are irrational combinations too which do not have an Ayurvedic justification. The other prominent problem of proprietary drugs is the difficulty in the understanding of a prescription containing them. A proprietary name, known by one physician may not be equally known by the other. This causes an ambiguity in the prescriptions and defeats the objective of writing a prescription as a piece of reference document for its possible use in future [11].

There had also been hues and cries about the possible nexus of pharmaceutical companies and physicians for their mutual gains.

Because of these reasons, generic drugs have always been promoted at ethical and regulatory forums regulating the drug use in a country. Govt. of India, walking on similar lines, has launched the Affordable Medicines and Reliable Implants for Treatment (AMRIT) scheme in 2015 with its initial outlets at AIIMS. These retail outlets are selling generic drugs for cancer and heart patients at highly discounted rates [12]. National Pharmaceutical Pricing Authority (NPPA) is a regulatory body in India looking after the pricing of controlled drugs with a primary motto of affordable medicine to all [13]. Unfortunately, so far, Ayurvedic drugs have not been brought into the ambit of such organizations and hence are still free from pricing regulations.

Using *rasa* preparations is another marker of trend of Ayurvedic practices belonging to a particular institution, area or practitioner. *Rasa* preparations in a prescription are important to be observed for many reasons. First and foremost is that these formulations by and large are composed of heavy metals of which mercury is often an essential component. Besides mercury, there may also be many other metals like iron, copper, zinc, lead, tin, gold and silver. Dose dependent toxicity is a known cause of drug adversity and is reported in Ayurveda in particular to the cases where more than one

formulation containing a common component is prescribed to a patient [14]. Toxic effects of heavy metal components of Ayurvedic drugs are a matter of global concern and debate. Although often argued by Ayurveda that such metals are duly processed in Ayurvedic formulations to render them non-toxic and of desired therapeutic value, it remains unable to counter the reported toxicities [15]. The other caution about *rasa* preparations is pertaining to their cost. Compared to herbal preparations, *rasa* preparations are highly expensive and in case of their containing precious metals like gold or silver, a manifold increase in cost is observed. It is simple to infer that any injudicious use of *rasa* preparations in Ayurvedic prescriptions not only exposes the patients for unforeseen adversities due to its undesired ingredients but also forces them to pay extra for the treatments which they do not require.

Present study identifies a few interesting trends of Ayurvedic prescription writing in the particular center. First thing requiring attention is the non-adherence to EDL for the purpose of drug dispensing. It is observed that the drugs available in the hospital dispensary are derived from a list made almost 25 years back, composing of 40 medicines. Although the list contains a few drugs which are also listed in EDL, majority did not find a place in the same. It is therefore important to infer whether EDL made by Ministry of AYUSH really serves a purpose. The drugs of EDL are usually made available in the CGHS dispensaries. Very recently, under the mandate of National AYUSH Mission (NAM), Ministry of AYUSH has started supplying the EDL of Ayurveda and Unani medicines to state run dispensaries also. Unfortunately, the Ayurveda colleges are still kept away from the scheme and hence they rely solely upon their own wisdom and resources in the matter of drug choice. This is one important reason why the study was not able to decipher whether the number of drugs prescribed were actually drawn from the EDL.

Among the prescriptions screened, it was found that on an average, 6.14 drugs were prescribed per prescription. The minimum number of drug prescribed was 1 whereas the maximum was 16. We see that there is great variation in choosing the number of drugs per prescription. We are aware that for precise diagnosis, often lesser number of drugs are required compared to an ill diagnosed condition. This simply says that, more the number of medicines, less likely is the confidence of the physician in treating the condition. An increasing number of prescribed drugs in prescription is observed recently and it is noted that the number of prescribed drugs per prescription in allopathy increased three fold in past 15 years [16]. Although there are no such data available pertaining to Ayurveda to make a comparison, we may presume that the number which is higher than average in Ayurvedic prescription is an indicator of a poor quality prescription. This inference however is required to be reinforced through observations at multiple places to the generalizability of the trend. Among the total drugs prescribed, the ratio between classical and the proprietary drugs was found to be 4:1. Although conceptually classical formulations are preferred over proprietary drugs for the reasons addressed above, we also need to understand that for the development of science, continuous research over the existing knowledge is required to improve it further. If the proprietary drugs are the outcome of such idea, their growth should not be restricted. The ratio observed in the present study between classical and the proprietary drugs (4:1) presents a fairly balanced proportion where classical drugs are predominantly used and are added with proprietary drugs only when it is really needed.

The *rasa aushadhi* prescription in the study is found to be 6.24% of total drugs prescribed. Among all, 81 (33.06%) prescriptions were found containing *rasa* preparations. We see that the herbal and *rasa*

preparation ratio among the prescriptions amounts to 2:1 which reflects a substantial *rasa* preparation use in the prescriptions. Moreover, the maximum number of *rasa* drugs prescribed in a single prescription was found 5 which again marks a question against the rationality of using such high number of *rasa* drugs in a single prescription.

A rational prescription in Ayurveda should be the one where every component on the prescription may it be drug, or procedure is justified on the basis of existing knowledge about the disease processes and its management on the basis of existing evidences. Any unfair, irrational and imbalanced prescription writing should be discouraged. Seeing this, this study seems to present a novel approach of screening Ayurvedic prescriptions on the basis of WHO tools of rational prescription. Although done on a small sample number and at one center only, the study proposes the potential of utilizing the same tool for larger studies and at multiple centers to screen the trends of Ayurvedic practice at large and to help re-correcting the trends if anomalies are identified in any of such practices.

5. Conclusion

Ayurvedic prescriptions have never been screened for their rationality on the pretext of individualization of the prescription based upon the knowledge of the prescriber and also the individual susceptibility and need of the medicine. It is however observed that Ayurvedic prescriptions are not free from anomalies and hence the corrective measures may be required. The biggest places where irrationality is found in Ayurvedic practice is the preferred use of proprietary drugs over generic drugs, *rasa* drugs over herbal drugs and procedures over medical management. Surprisingly, all these trends have a possibility to be caught by a simple observation of the trends of practice in a setting using WHO drug use indicators. Although such indicators have been developed for the allopathic drug usage, they can find an easy application in Ayurveda by making a simple modification as is done in present study. The study was able to identify some alarming trends of preferences of some class of drugs over the other. It has also shown the way in which this can be used as a most useful tool to screen the trends in Ayurvedic prescription writing and hence to improve it further if some irrationality is found in the practice belonging to an institution, area or individual.

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Conflict of interest

None.

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