Original Research Article

DEVELOPMENT OF A TOOL FOR ASSESSING PATIENT COMPLIANCE ON VARIOUS AYURVEDIC FORMULATIONS USED FOR INTERNAL ADMINISTRATION

ABSTRACT

Introduction: Compliance is a process where the patient follows the prescribed and dispensed regimen as intended by the prescriber. Poor compliance has been reported as it is the most common cause of non-response to medication. There is no single best indicator to assess patient compliance in Health Research. This study aims to develop and validate a new questionnaire considering the pharmaceutical properties of Ayurvedic medicines to measure patient compliance.

Method: The first phase consisted of a qualitative phase to identify the variables to measure patient compliance through in-depth interviews among five doctors and focus group discussion with eight practitioners, and pre-test with respondents, experts, and peers. The second phase was a quantitative phase to assess the respective responses of patients towards the questionnaire through a cross-sectional survey among 106 subjects as a pilot study.

Results: The qualitative analysis reported variables which were seen spread across eight domains were used to measure compliance.

Conclusion: Ayurvedic treatment is personalized and there is always a scope for a remake of formulation designing for each individual. Sticking on to appropriate prescription after properly assessing the needs of the patient and the reason for their non-compliance can bring a revolution in terms of cost-effectiveness and time. The wastage of medicines, whether raw drugs or the processed ones, can be prevented by recognizing the factors for non-compliance. There is always a scope for improvement with further alike or more developed research in patient compliance in Ayurveda.

Key words: Patient compliance; Ayurvedic medicine, Tool, Qualitative analysis, Palatability

Introduction

Patient compliance consists of a complex and multidimensional health issue globally. To explore the perceptions and acceptance of Ayurvedic medicines, particular tools are not available. Patients' acceptance is otherwise patients' satisfaction. Compliance is defined in several ways. The interpretation of the term depends on the philosophical context during which the concept is settled.[1] Compliance is a process where the patient follows the prescribed and dispensed regimen as intended by the prescriber and dispenser.[2] Poor compliance has been reported as it is the most common cause of non-response to medication.[3] Unit evidence shows that patients who adhere to recommendations have better health outcomes than people who do not adhere.

It has been observed from previous studies that several components are involved in patient compliance. Compliance, the oldest term to explain medication-taking behavior seems to suggest a single-sided interaction where the clinician decides on the appropriate treatment, which the patient has to adjust to no matter its suitability. The terms compliance, adherence, and concordance are often used interchangeably in research and clinical practice.[2]Even though related, they do possess slight differences. WHO states that non-adherence to medication may be a "Worldwide problem of striking magnitude".[4] WHO also defines adherence as "the extent to which the person's behavior (including medication taking) corresponds with agreed recommendations from a healthcare provider.[5] WHO in a trial to cut back the paternalistic nature of the term 'compliance', introduced the term 'adherence'.[1]According to WHO, various factors are leading to medication adherence, which are normally classified into 5 categories.[6]

1) Socio-economic factors

2) Patient-related factors

3) Therapy-related factors

4) Condition related factors

5) Health-care team-related factors

The factors associated with a characteristic of the disease, patient's socio-economic factors, poor efficiency, medication side effects, duration of treatment, the severity of the disease, long period medication are the determinants of patient compliance.[2]

Demographic and disease factors have generally been found to be pure indicators of compliance. Patient's relationship to parents or relatives and participation of spouse in treatment enhances compliance.[3]

The duration of therapy could be a factor that may influence the extent of compliance. Compliance with short-term medications is usually considered to be somewhat more than that for long-term medication regimens. The typical rate of compliance tends to converge to 50% for long-term therapy, no matter disease, and compliance behavior tends to lessen with time.[7] The increasing prevalence of 3 chronic conditions where long-term therapy is prescribed suggests that compliance will still be a region of concern.

The long duration of treatment, a high number, and the high cost of medication are found to be negatively influencing compliance and the fear of the adverse effect of the medication is

additionally a reason for non-compliance.[8] Unfortunately, all these factors are heavily contributing towards the non-compliance in case of Ayurvedic medications. Still, no study has been conducted towards the assessment and improvement of patient compliance of Ayurvedic medicines due to lack of tools available.

Compliance is measured directly and indirectly. Direct measurements of compliance usually involve the detection of a chemical in a very bodily fluid.[1] Indirect measurements of compliance include therapeutic or preventive outcome, the impression of the physician or predictability, patient interview, prescription filling dates, and pill counts.[9]

'Concordance' suggests that patients should take more responsibility even if no one is willing to try this.[1] The term 'concordance' doesn't take under consideration the cases where some patients refuse treatment either because they are unaware of the cost and benefits or likely to be hurt. [10] Methods of measuring adherence can be classified as direct method and indirect method. Direct methods include directly observed therapy, measurement of drug concentration in blood, and measurement of the biological marker within the body.[4] Indirect methods [11] include

- Patient self-report or questionnaire is one of the important indirect methods of measuring medication adherence and persistence and it is the foremost commonly used method within the clinical setting.
- Pill counts
- Pharmacy fill data
- Electronic medication monitoring
- Assessment of the patient's clinical response

Some interventions can be done to boost patient compliance.

- Educational strategies like verbal communication or counselling are shown to boost compliance.[12] Written information is also effective for short-term medication therapy.[13]
- 'Behavioral strategies like reminders and special medication containers are shown to boost compliance.[14]
- Compliance can best be improved to a great extent by interventions combining educational and behavioral components.[15]

Morisky Medication Adherence Scale (MMAS): A adherence scale for medicament should be able to accurately capture the beliefs, barriers, and behavior associated with medication adherence. It should even be easy to administer, understand, and be precise.[16] In 1986, Dr. Morisky and his colleagues published this instrument. The primary Morisky scale has four items that have dichotomous response categories with yes or no.[17] In 2008, a modified eight-item Morisky Medication Adherence Scale(MMAS-8) was developed from the first four-item Morisky scale.[18] The primary 4 seven items were dichotomous response categories with yes or no and also the last item was a five-point Likert response. MMAS-4 and MMAS-8 are designed to explain the medication-taking behavior of patients but they appear to be ineffective in comprehensively assessing the reasons or predictors of medication adherence.

They are good estimates of the medication-taking behavior, and good screening and monitoring tools to spot those patients who might possess medication adherence problems. These scales help to recognize and monitor high-risk non-adherent patients. But they are not good explanatory tools for inferring why patients are not adherent, which can cause a poor relationship between the Morisky scale and objective clinical outcome measures.[4] In a study, it had been found that blood glucose levelswere not related to Morisky scale scores.[19] MMAS-4 was not valid for patients taking antihypertensive medications in Germany.[20] It has to improve in terms of translational validity including face validity or content validity.

Other medication adherence scales.[21]

1. Beliefs about Medicines Questionnaires (BMQ)
2. The Medication Adherence Rating Scale (MARS)
3. Adherence Self-Report Questionnaire (ASRQ)
4. Adherence Starts with Knowledge 20 (ASK-20)
5. Hill-Bone Compliance Scale

Patients' perspective on medication taking, which may be a key component of compliance/adherence behaviors was neglected by researchers for a long time.[7] However since the 1990s this area has been focused on and suggested that patients' view on medication plays a key role in determining compliance/adherence. In modern medicine, the extent of non-adherence in asthma/COPD, cardiovascular diseases, and other diseases are usually studied.

Ayurveda pharmaceutics or Bhaishajya Kalpana deals with a variety of dosage forms including primary and secondary dosage forms having different therapeutic utility. The distaste of drugs and their large dose are the chief factors that influence the compliance of patients towards Ayurvedic drugs. In the present era in which Ayurveda is gaining global recognition, these factors should be tackled well to achieve acceptance for Ayurvedic medicines. Nowadays, there is a wide choice for treatment and to ensure the global acceptance of Ayurveda more people should opt for Ayurveda too. This is possible only by identifying the reasons or explanations behind denying Ayurveda and further steps can be taken to rectify them accordingly.

To better understand medication-taking behavior, researchers need to examine the patients' perspective. Till now, there is no gold standard method to estimate the medication-taking behavior of patients.[4]

Non-compliance to Ayurvedic medication used for internal administration is commonly observed. Hence to explore new strategies to enhance better compliance and better clinical outcome without compromising the fundamental concept of Ayurveda, this study was conducted. The truth is that many patients experience difficulty with medication-taking resulting in suboptimal adherence. As health-care professionals, we have a vital role in combating this problem and hence an attempt was made to develop a tool for assessing patient compliance on Ayurvedic medicines used for internal administration. The present era demands the development and validation of a scale for measurements in accordance with

Ayurvedic concepts. The various factors leading to non-compliance in an individual are important and should be identified before establishing practical ways of developing a concept to increase compliance rates.

A unique combination of the *padachatushtayas* mentioned in Ayurveda with its prescribed qualities is of utmost importance. Among *Chatushtayas*, the *vaidya* stands supreme because of possessing true knowledge by which he selects the drugs for patients based on his *Prakriti*, *Desa*, etc. In many aspects, Ayurveda focuses on personalized medicine, the role of patients in the global acceptance of Ayurveda is never too low. The suggestions and modifications should come from their experiences and knowledge as well. This study is designed with the objectives to develop a valid and reliable tool for assessing patient compliance and to trace out the problems faced by patients while taking Ayurvedic medicines.

Methodology

The mixed method study was conducted in sequential exploratory design.[22] (Figure 1)

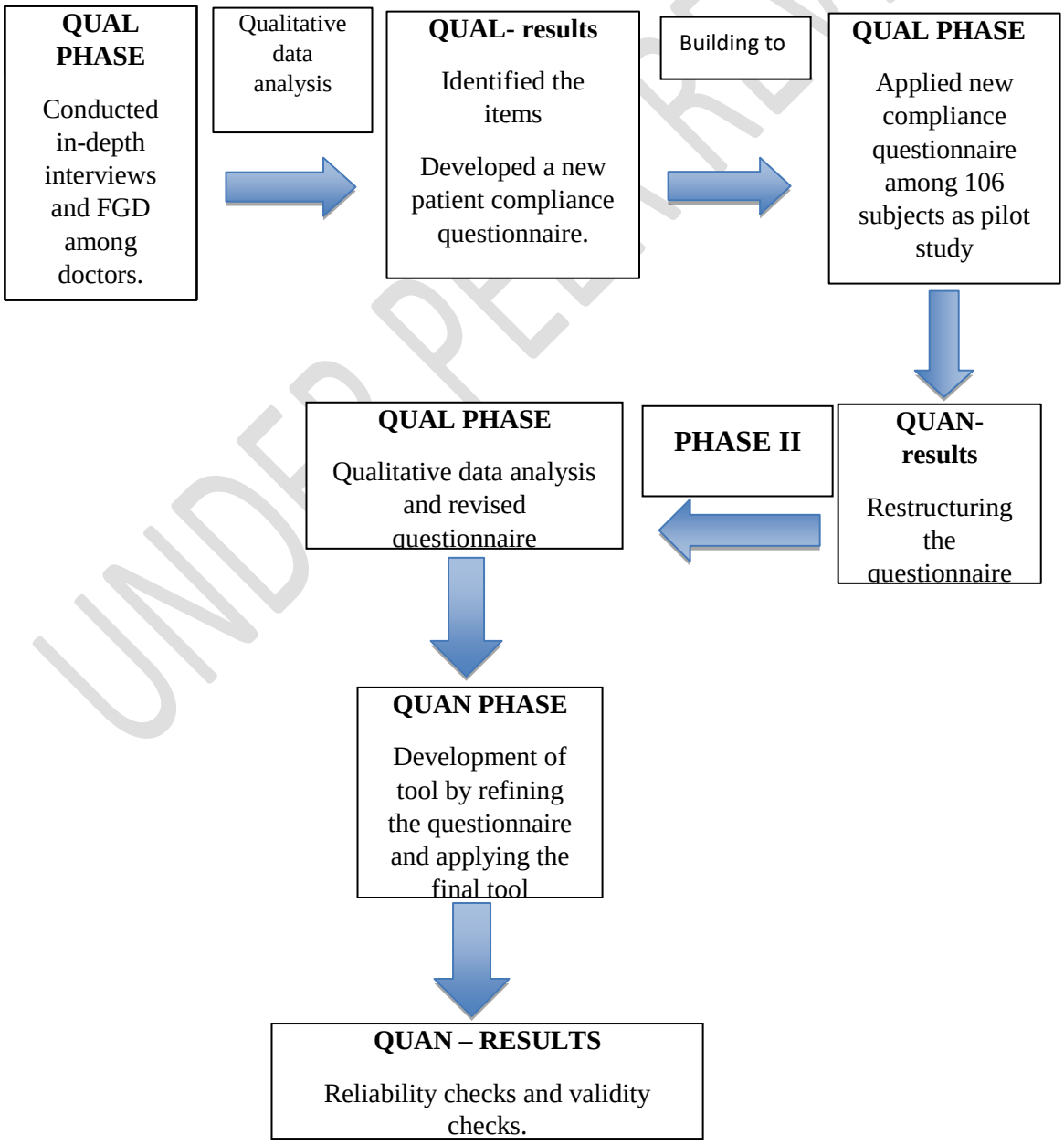

Figure 1. Plan for Sequential Exploratory study

Objectives

- **Primary objectives:** To develop a valid and reliable tool for assessing patient compliance.
- **Secondary objectives:** To trace out the problems faced by patients while taking Ayurvedic medicines.

DEVELOPMENT OF THE CONSTRUCT

Conceptualization

Detailed literary research was carried out to derive the concept of patient compliance. Experts from the fields of Ayurveda were interviewed for the collection of items and 15 items were selected. Each item was reviewed to correspond with the literary hints. Along with this, a focus group discussion was convened.

Operationalization of the construct patient compliance

Compliance can be defined in various ways. The interpretation of the term depends on the philosophical context in which the concept is settled.

2. Item generation

Items in the tool was generated based on review of relevant literature, in-depth interview with experts, getting respondents' opinion and focus group discussion with experts. These processes ensured the inclusion of various dimensions of concept and appropriate items under specific domains.

Collecting items from experts

Experts from the fields of Ayurveda were interviewed for the collection of items. A set of items already framed was discussed and each item was reviewed to correspond it with the literary hints. Along with this, a focus group discussion was convened.

Focus group discussion (FGD)

Focus group discussion was conducted in order to get the perceptions, opinions and attitudes regarding compliance. (Figure 2)

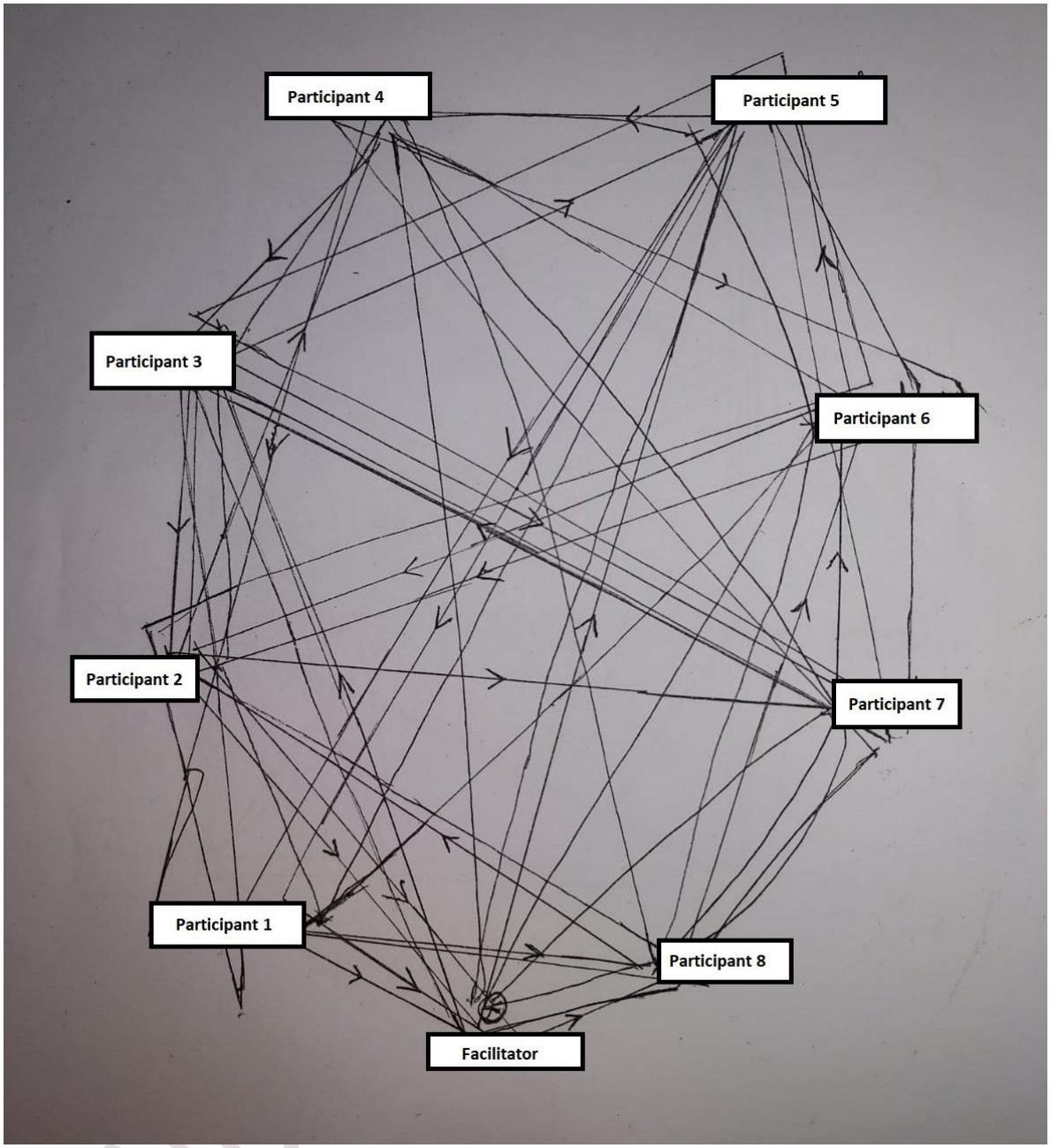

Figure 2 – Sociogram of FGD conducted

Selection of subjects in FGD

Individuals chosen for FGD were familiar with the subject and were known for their ability to respectfully share their opinions, and were willing to volunteer for about 2 hours.

Contacting and informing participants

The initial contacting of participants was done by mail, telephone, and in person. On the previous day, the participants were all contacted personally by the investigator and their presence was ensured. Facilitator was the investigator herself. The discussion was led by a moderator (investigator) assisted by an observer who took notes and did arrangements. Participant's opinion about the topic was asked. It was ensured that they felt comfortable

while sharing their opinion. Participant size was decided as 8. Topic of discussion was based on the components involved in patient compliance. The drug related factors influencing compliance were highlighted. Determinants of non-compliance related with pharmaceutical aspects of drug were mainly considered.

Fixing the variables: Pharmaceutical dosage forms, palatability of different dosage forms, frequency of medicine intake, poly-pharmacy, availability of medicines, medication cost, severity of illness, duration of treatment, fear of medicine interaction with allopathic medications, poor efficacy of medicines, time of administration, colour of medicines, particular odour of certain dosage forms, doctor-patient relationship, *pathya-apathyas* were discussed.

Item selection: The items were again discussed by experts in detail and once again they were checked whether to keep or discard. From 15 items, 8 items were selected. (Figure 3)

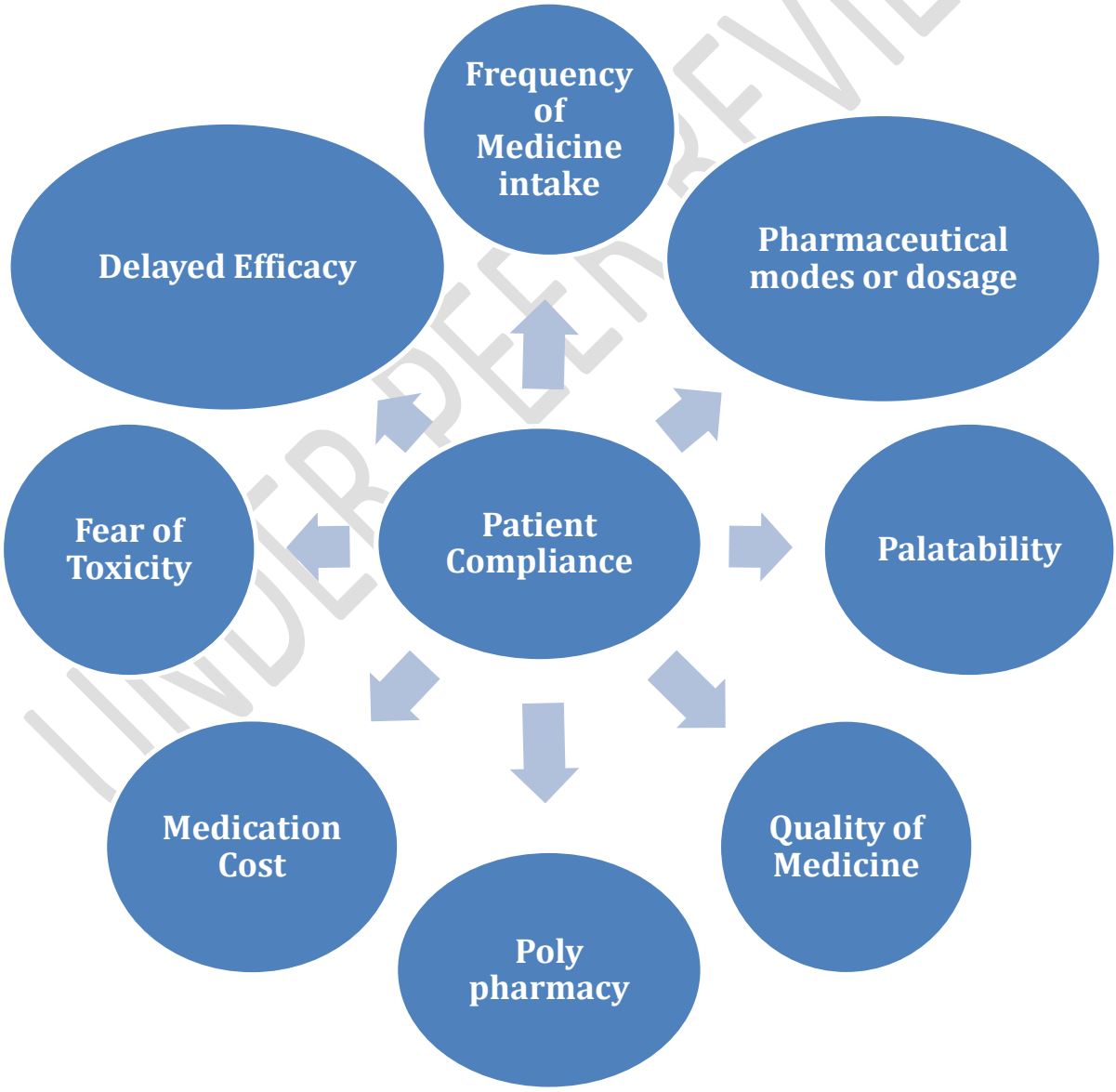

Figure 3 – Domains of Patient compliance

Formatting the questionnaire

Data analysis was done at three levels: open, axial and selective coding. Open coding was a line by line scrutiny of the data, to identify the codes expressed by the participants. Fifteen quotes related with compliance emerged from the data. Labelled the related quotes and grouped them into categories in axial coding. The next step was to identify a core category, which related to all other categories at the selective coding stage.

All the codes were taken as variables. These variables were converted into questions. Selected simple wording for each question to ensure the acquiescence of the questionnaire.

3. Item wording, sequencing and formatting

Selected items were worded appropriately to suit the level of comprehension of the respondent population of patients using Ayurveda medicines and sequenced from general to specific. Discussions on structure of questions and response were made and questions were analysed.

Cognitive piloting

Cognitive piloting was done for identifying problems with question wording comprehension and recall and for ensuring that items are capturing the underlying construct.

4. Scoring pattern

Giving equal weightage to all items, scoring was done.

5. Translation and back translation

Items were translated into the local language Malayalam. Items were translated back to English by 2 linguistic experts. It was particularly made sure that the meaning was not altered in translation.

6. Pretest

Here, before a full-scale study, a questionnaire is tested on a statistically small sample of respondents in order to identify problems related with wordings.

Method followed for pre-test are as follows

Expert review

The items were reviewed by experts to comment on format, clarity, and to ensure content coverage and simplicity of items in the tool.

Peer review

The translated tool was given to peers.

Respondent's review

Questionnaires were administered to the respondent population to test the wording and comprehensibility.

7. Pilot study

For pilot study, 106 individuals were randomly selected. The comprehensibility of the questionnaire and the anticipated logistic issues that can occur during the final administration of the questionnaire were tested.

Description of the questionnaire: Self-administered questionnaire was developed in the official language of Kerala (Malayalam). Response of the questionnaire was made in a mixed format. It included dichotomous questions, multiple choice questions and open end questions. The online semi-structured questionnaire was developed in Google forms. The link of the questionnaire was sent through emails, WhatsApp and other social media to the contacts of the investigator and the survey was conducted. The process of the questionnaire development and its piloting is being represented as a flow chart (Figure 4).

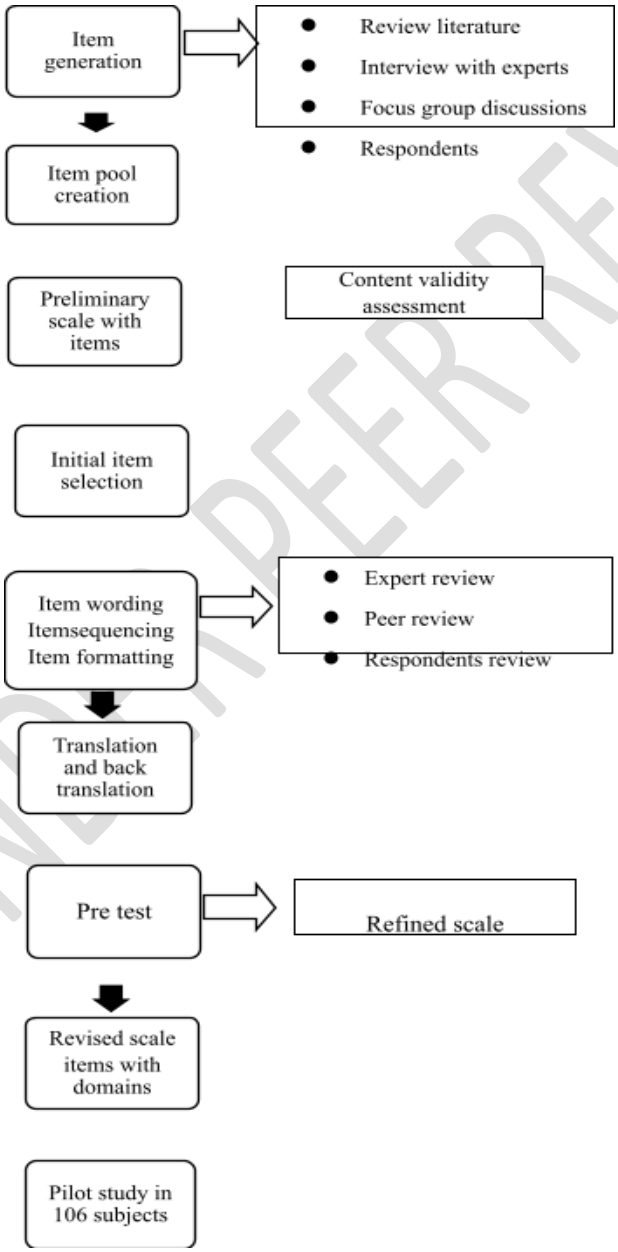

Figure 4 – Flow chart of the questionnaire development process

Analysis of the survey

Out of 106 responses, about 53.8 % of participants mentioned that the taste of medicines affected the consumption of medicine. (Figure 5) Among them 64.4% participants showed hatred towards medicines with bitter taste, 62.7 % towards astringent, 8.5% towards pungent, 5.1% towards sour and 1.7% towards sweet taste. No aversion was mentioned for the medicines with salt taste. 39.6% of the participants mentioned that the taste did not affect the consumption of medicine. 6.6% participants were not sure about the question.

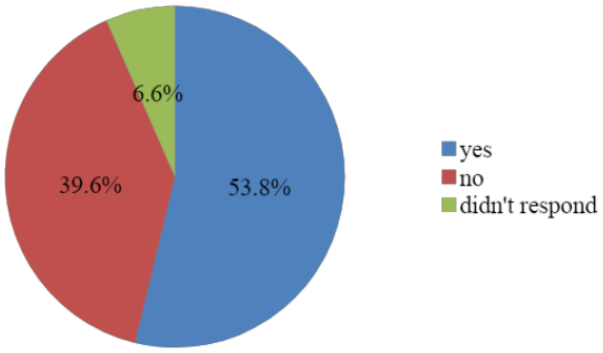

Figure 5. Pie chart showing distribution of opinion on whether taste of medicines affected the consumption of medicine.

About 54.7% of participants mentioned that the form of medicine affects their medicine consumption. Among them 36.7% showed dislike towards medicines in the form of ghee, 35% towards *Kashaya*, 25% towards oil, 23.3% towards *Churna*, 3.3% towards *Arista*, *asava* and tablets and 1.7% towards *Lehya* form of medicine. 35.8 % responded that the different forms of medicine did not affect the consumption of medicine. 9.4 % were not sure about the question. (Figure 6)

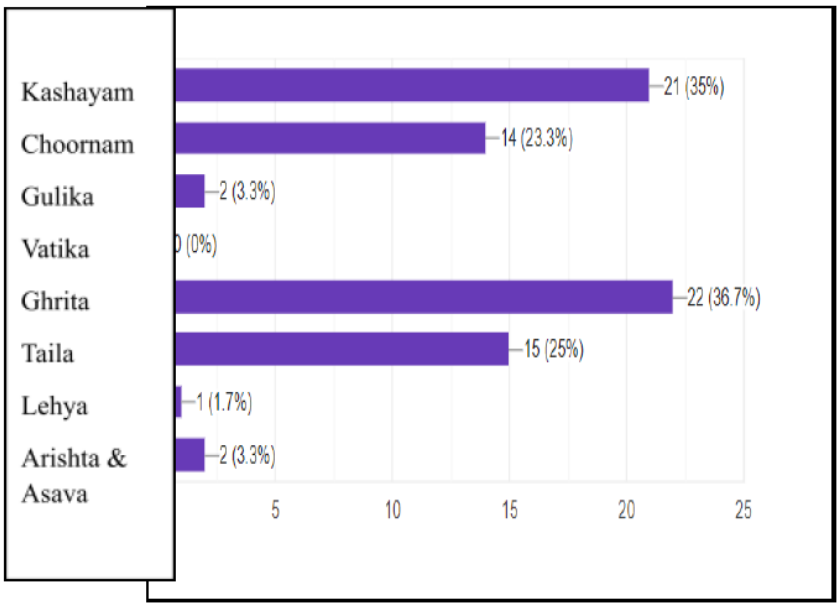

Figure 6. Distribution of opinion on which form of medicine affected their medicine consumption negatively,

71.7% participants mentioned that the increased dose of Ayurvedic medicines did not influence the usage. But about 19.8% showed dislike towards the increased dosage. 8.5% participants were not sure about the question.

In 57.5% participants, the increased expense of Ayurvedic medicines did not adversely affect the medicine intake. But in 33% participants it adversely affected. Repeated dosage of Ayurvedic medicine hinders the medicine usage in 39.6% participants, but not affected in 50%. Consumption of more than one medicine in the prescription did not affect 59.4% participants but it adversely affected 31.1%.

About 34% of participants were possessing fear towards side effects of Ayurvedic medicines. When asked about the reasons behind this response, various responses include fear of heavy metal content, lack of proper testing of drugs, drug interactions when used along with allopathic medications and the presence of preservatives.

Delayed response of Ayurvedic medicine was mentioned by 43.4% participants. While 41.5% believe that delayed response does not influence the consumption of Ayurvedic medicines. (Figure 7)

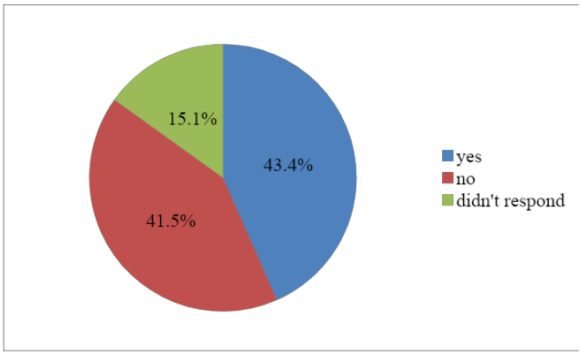

Figure 7. Pie chart showing distribution of opinion on whether delayed response influence the consumption of Ayurvedic medicines.

57 members tried to obey about more than 80% of advice from doctors regarding intake of medicine, 34 responses showed following 60 to 80%, 8 responses towards 40-60% and 7 responses showed following below 40% of doctor's advice. (Figure 8)

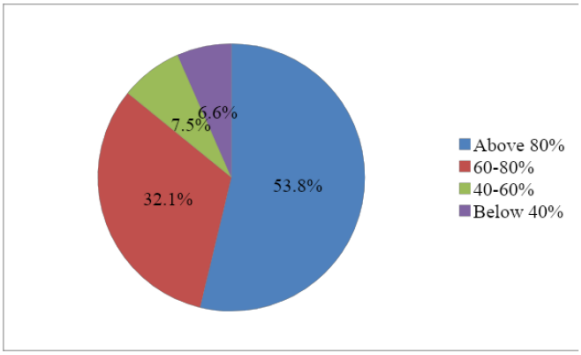

Figure 8. Pie chart showing distribution according to how much percentage of advice from doctors are followed regarding intake of medicine.

DISCUSSION

In Ayurveda the *Padachathustayaas* or the quadruples of treatment are mentioned which includes *Bhishak*, *Dravya*, *Upasthatha* and *Rogi*. A unique combination of the *Padachatushtayas* mentioned in Ayurveda with its prescribed qualities is utmost important. Among *Chatushtayas* the *Vaidya* stands supreme as the one enriched with exact knowledge and gained practical training and at the same time hygienic can conquer any disease if the other quadruples with suitable qualities unite.

The main tool of a doctor is the medicines and as per Acharyas a drug or *Aushadha* should possess multiple properties, possible to be transformed to various formulations, enriched with active principles and be desirable to be employed in many disease conditions. The likelihood to remodel to numerous formulations can make the drug acceptable to patients by overcoming the hurdles like distaste, large dose etc.

Distaste of drugs and its large dose are the chief factors which determine the compliance of patients towards Ayurvedic drugs. In the present era where Ayurveda is gaining global recognition, these factors should be tackled well to achieve a quick acceleration. But simultaneously a good patient should consider the words of the doctor and follow them accordingly, then only the treatment will become successful. In earlier time this was practical, but nowadays, there is a wide choice for treatment and so as to ensure the global acceptance of Ayurveda more people should come there too. This is possible only by identifying the reasons or explanations behind denying Ayurveda and further steps can be taken to rectify them accordingly.

Bhaishajya Kalpana deals with a variety of dosage forms including primary and secondary dosage forms having different therapeutic utility. Primary *Kalpanas* are *Swarasa, Kalka, Kashaya, Phanta* and *Sheeta*. Secondary *Kalpanas* include *Ghrita, Taila, Asava, Arista, Vatika* etc. Though primary *Kalpanas* have much importance compared to other *Kalpanas*, they even have some disadvantages. The main disadvantages of primary *Kalpanas* are reduced shelf life, physician's discomfort to be ready with fresh drugs always, as all drugs are not available at all places and seasons. Moreover, the bitter and pungent taste, large dose, longer duration taken for efficacy to come to play etc. also stand as demerits. As *Swarasa* and other *Panchavidha Kashaya Kalpanas* are having very less shelf life, they are difficult to be manufactured, dispensed on a large scale and to be marketed.

Main disadvantages of *Kwatha Kalpana* are difficulties in ensuring quality control of the herbal ingredients, time and inconvenience required in preparation, transportation, storage and probable loss of active ingredients. It is also difficult to prescribe in an accurate dose. These are prepared in aqueous media, and this decreases the stability of the product. In case of hot water, starch gets dissolved providing favourable media for the growth of moulds and bacteria or bring about the decomposition of the product. The presence of sugars or other carbohydrates results in alcoholic fermentation with the evolution of CO_2, while the presence of protein leads to nitrogenous fermentation with the liberation of ammonia. Exposure to atmosphere and light accelerates spontaneous oxidation of the preparation which results in unpleasant odour and taste and it becomes rancid. Another

demerit is that a part of volatile contents present in the raw materials are lost in the course of preparation of *Kwatha*. To overcome these disadvantages, modifications should be made.

The major processes involved in the modification of the primary dosage forms include drying of the raw drug, heating of the formulation and thereby making it into thicker consistency, addition of sweetening agents, fermentation, packing and containers used in storage or preservation. Since the main aim of modification is to retain the therapeutic efficacy of the dosage form, improved shelf life and increased palatability the various further processes are carried out. By heating, the moisture content if any present in the formulation or in the raw drug is removed, thereby preventing susceptibility to microbial attack.

CONCLUSION:

The questionnaire filled by the participants after filing their consent is a data generation based on their own unbiased opinion. But they don't give the causes for their opinion or for the hatred towards some particular medicines. This might be attributed to the lack of awareness of pure Ayurveda in the society. Sometimes a family with an older generation only has an inclination towards Ayurveda. In Ayurveda, different varieties of formulations are available. There is always a scope for remake or formulation designing with respect to each individual. Moreover, the treatment in Ayurveda is also personalized after assessing *Dushya, Desha, Bala, Kala, Agni, Vaya, Satwa, Satmya, Prakrti* etc. Sticking on to appropriate prescription after properly assessing the needs of patient and reason for their non-compliance can bring a revolution in terms of cost effectiveness and time.

The wastage of medicines can be prevented whether raw drugs or the processed ones by recognizing the factors for non-compliance. In a way, being the flag- bearers of Ayurveda, we are dutiful to cause a change in misconceptions of the society like the uncertainty of effect of Ayurvedic medicines, fear of adverse effects, long duration taken for effectiveness of medicine etc. This way, the acceptability and promotion of Ayurvedic science can be sought. There is always a scope for improvement with further alike or more developed research in patient compliance in Ayurveda.

LIMITATIONS:

The pre-test was done in a single hospital.

The survey could be conducted as online only which prevented data collection from ground zero level.

Exploratory factor analysis was not done. Hence, it is not sure whether the theoretical constructs match with those obtained on data analysis. So, a readily usable patient compliance tool, which can be applied in a clinician's table top was not developed.

SUGGESTIONS:

Study can be done in patients of different areas and then only results can be generalized.

To determine the magnitude of the problem faced by patients, FGD can be done in patients suffering from different diseases.

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