

ORA- Observational Study

Exploring the Prognostic Utility of Tailabindu Pareeksha in Malignancy - A Pilot Observational Cohort Study

¹Reshma K, ²Darshna Pandya, ³V. J. Shukla

ABSTRACT:

Introduction: Prognosis serve as a critical bridge between diagnosis and treatment. Prognosis can be drawn on the basis of *Tailabindu Pareeksha* explained under *Ashtasthana Pareeksha* by Yogaratnakara. This test was popular during the medieval period but got outdated with time. In this test, a drop of sesame oil is dropped over the midstream urine sample and prognosis is predicted on the basis of the direction of spread of oil drop and the shape made by the oil drop after spreading. Malignancy is a grave disease with abnormal growth and uncontrolled proliferation, so given the high morbidity & mortality rates of malignancy, it serves as a convenient disease to study the prognostic aspect. **Aim:** To evaluate the prognosis of patients with malignancy (irrespective of type) using *Tailabindu Pareeksha* and compare its results with ECOG (Eastern Cooperative Oncology Group) scale and explore the feasibility of MATLAB assisted mathematical prediction model. **Materials and method:** A total of 26 patients were enrolled in case (Group A) and 25 subjects in healthy group (Group B). Among the 26 enrolled patients, 13 had completed the study with 3 follow-up visits, during which *Tailabindu Pareeksha* was done and the findings were compared with respective ECOG scales. **Result:** Outcomes of *Tailabindu Pareeksha* suggested that the association of shape and direction with ECOG scale were significant ($P < 0.05$) during the initial time but, during the first and second follow up it showed variation in statistical significance. The reduced number of subjects might be a contributing factor for this variation. **Conclusion:** *Tailabindu Pareeksha* showed a possible association with the changes in scores of ECOG, however due to the pilot nature of the study, limited sample size and participant dropout during follow up, the result should be interpreted cautiously and larger prospective studies are required to further understand its prognostic utility in malignancy.

KEYWORDS: ECOG, Malignancy, *Mutra Pareeksha*, Prognosis, *Tailabindu Pareeksha*, Urine examination.

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1. INTRODUCTION

Ayurveda, the ancient Indian system of medicine, emphasizes disease prevention and holistic treatments by maintaining the balance of *Dosha* and *Dushya*. Any derangement in this balance leads to disease. In order to diagnose diseases and to know their prognosis, various *Roga Rogi Pareekshas* (examination of the disease and the patient) are available in Ayurveda. Prognosis of disease is also explained in Ayurveda under the label of *Sadhya-Asadhyata*. *Tailabindu Pareeksha* is an ancient method of prognosis for any disease in general. This is explained under *Ashtasthana Pareeksha* by Yogaratnakara. [1] Other than this text, Vangasena Samhita, [2] Basavarajeeya, [3] Yogatarangini [4] also explained *Tailabindu Pareeksha* separately. This test was popular during the medieval period but got outdated with time. It is usually performed to understand the *Dosha* predominance as well as disease prognosis. In this test, a drop of sesame oil is dropped over the morning midstream urine sample collected in a glass vessel. Prognosis is interpreted based on the direction of spread of oil drop and the shape or pattern made by the oil drop after spread. [5, 6]

Malignancy is a grave condition in which abnormal cells divide without control and can invade nearby tissues. Malignant cells use blood and lymphatic systems to spread to other body parts; it ranks as a leading cause of premature death, [7] and is an important barrier to increasing life expectancy in every country of the world. Cancer prognosis depends on the stage of diagnosis. The TNM staging approach is the accepted approach for cancer assessment and it relies upon tumor size and extend (T), lymph node presence (N) and distant metastasis (M) in order to estimate treatment success and prognosis. [8] Early stages (0 and I) are characterized by good survival rates and cure potential, intermediate stages (II and III) have reduced survival due to larger tumor burden and regional spread. Advanced cancer is associated with the distant metastasis in stage IV and poor prognosis as well as predominantly palliative treatments. [9] Thus malignancy is a

global burden with its prognosis depends mainly on disease stage, in which an early diagnosis will give a good prognosis, and the delay cause a grave prognosis. So, it is a convenient disease for which a prognostic tool can be developed.

Scientific literature illustrating prognostic application of *Tailabindu Pareeksha* in cancer is limited. A recent review has summarized the classical concepts and possible scientific basis of *Tailabindu Pareeksha*. [10] Only one study has evaluated the prognostic utility of *Tailabindu Pariksha* in malignancy with concluding necessity of further validation and data generation. [11] As, the study was limited by a small sample size and absence of a structured accuracy or prognostic model. The current study solves these knowledge gaps through both experimental evaluation and theoretical model assessment. So, present study hypothesized that *Tailabindu Pareeksha* findings may reflect variations in ECOG performance status among malignancy patients.

Aims:

1. To evaluate the prognosis of malignancy (irrespective of type) patients by *Tailabindu Pareeksha*.
2. To explore the feasibility of a MATLAB assisted mathematical prediction model based on *Tailabindu Pareeksha* parameters for understanding prognosis in malignant patients.

Objectives:

1. To identify different shapes made by the spreading of oil drop over the surface of urine sample and classify the condition in to curable & incurable Category.
2. To evaluate the prognosis of malignancy patients by *Tailabindu Pareeksha* as well as ECOG Scale
3. To compare the results of *Tailabindu Pareeksha* with ECOG Scale

2. MATERIALS AND METHODS:

An observational prospective cohort pilot study was carried out in Institute for Postgraduate Teaching & Research in Ayurveda in collaboration with G.G Govt hospital, Jamnagar. This study

was approved by the Institutional Ethics Committee of IPGT and RA (Approval No: PGT/7/-A/Ethics/2020-21/611; dated 10/07/2020) and was prospectively registered under CTRI Reg. No: [CTRI/2020/11/029380](https://ctri.nic.in/Clinicaltrials/showstudy?ids=CTR1/2020/11/029380) on 26/11/2020.

Informed consent: For clinical study written informed consent of all the patients was taken prior to registration.

The study was conducted from December 2020 to June 2022 with a total study duration of 18 months. Histo-pathologically confirmed and clinically diagnosed cases of any kind of malignancy, recommended for radio and/or chemotherapy and willing to participate in the study were registered for the present study irrespective of their age, gender, occupation and socioeconomic status after taking written informed consent. Patients were recruited from the OPD/IPD of the study setting and follow-up assessments were done during three consecutive follow-up periods (Group A, n=26). To observe *Tailabindu Pareeksha* in healthy subjects, 25 healthy volunteers were also enrolled as a separate group (Group B, n=25) and *Tailabindu Pareeksha* was performed only once in these subjects. Malignancy patients had to undergo for *Tailabindu Pareeksha* thrice i.e., before starting the therapy(baseline), very next day after completion of the therapy and one month after completion of the therapy (two follow-ups). A pilot study design was adopted considering the exploratory nature of the study and limited availability of prior data. The study aimed to generate preliminary observations and assess practicality for future large-scale investigations. So, formal sample size calculation was not done. The study size was determined based on feasibility and availability of eligible participants during the study period. The primary variables assessed in this study is the shape of the oil drop after spreading and the direction of spread of oil drop, these parameters were evaluated to find their association with functional status of patients with prognosis of malignancy. Area and time variables were additionally utilized for MATLAB-assisted computational and mathematical analysis. ECOG (Eastern Cooperative Oncology

Group) Scale is a developed prognostic tool and being used to guide treatment decisions and assessing prognosis in malignancy patients was used in all patients.

Group A:

Inclusion criteria: Histopathologically confirmed and clinically stage II cases of any kind of Malignancy, who recommended radiation and /or chemotherapy for further management, were enrolled. (Stage II was selected due to its stable clinical status, better functional capacity, and comparatively fewer complications than advanced-stage malignancies, thereby allowing more reliable assessment of study parameters and prognosis).

Exclusion criteria: Malignancy cases of Stage I or who entered in stage III or further, Malignancy patients who are terminally ill and on palliative medicine only and Individual not ready to abide by the study procedure.

Group B:

Inclusion criteria: Apparent healthy individual [12] having age between 20- 40 years (*Youvana* or *Sampoorna* stage of age) [13] were enrolled for the study as control sample.

Exclusion criteria: Individuals fulfilling criteria of being healthy and of age less than 20 and more than 40 years were excluded.

Control group was incorporated in to the study just to understand the urine spreading pattern in healthy individual, which in turn helps to differentiate the results in malignant group.

Tailabindu Pareeksha:

To minimize any physiological variation that may affect the spread and shape of oil drop, *Tailabindu Pareeksha* was performed as per the standardized method, [10] using morning midstream urine samples, identical glass vessels, and the same type of sesame oil for all participants. All observations were performed by the same investigator under similar examination conditions to minimize the observational bias. Blinding of assessors was not feasible in the present study due to the direct observational nature of *Tailabindu Pareeksha*.

Procedure: 12 µl of black sesame oil was dropped from a height of 1cm over the surface of morning mid-stream urine sample of patients collected in glass petri dish of 8-inch diameter. All observations were recorded in the form of video clips. Still photographs were taken from the clips afterwards for the assessment of shape, direction, area covered and time taken for spread of the drop of oil. The same *Tailabindu Pareeksha* was performed in healthy volunteers for once only. The assessment of this prognostic tests was based on the direction of oil drop spread which was assessed according to the predominant orientation of spread with the help of a compass and the shape of the oil drop was categorized based on geometric appearance of spread pattern, while area covered and time of spread were recorded additionally for MATLAB-assisted mathematical prediction model, area was determined by calculating the number of squares occupied by the completely spread oil pattern using a square-grid sheet and time was defined as the duration from the moment of placement of the oil drop on urine until completion of the spreading pattern. ECOG Scale was another criterion for evaluation as it is widely accepted and clinically validated tool for the assessment of malignancy patient's prognosis in terms of patient's level of functioning to care for themselves, daily activity, and physical ability. [14] Output of ECOG scale and *Tailabindu Pareeksha* was compared to evaluate their prognostic relevance. Here in this study, *Tailabindu Pareeksha* findings were evaluated as prognostic indicators, and changes in ECOG Performance Status and clinical outcomes during follow-up were considered outcome measures. For exploring feasibility of a MATLAB assisted mathematical prediction model, different combinations of *Tailabindu Pareeksha* parameters such as oil drop shape, direction, time of spread and area/blocks covered by the oil drop were tried to identify feature combinations potentially showing high accuracy. Statistical analysis:

Statistical analysis was done by using Sigma stat 3.1 software for windows. Data were expressed using appropriate

descriptive statistical measures. Categorical variables were analyzed using Chi-square test with Yates correction wherever applicable and McNemar test, Continuous variables were analyzed using independent t-test. A p-value <0.05 was considered as significant. However, Confidence intervals and effect size measures were limited and have been acknowledged for consideration in future studies with larger sample sizes.

3. RESULTS:

A total of 63 individuals were screened for eligibility for this study, 28 met the pre-defined inclusion criteria, however, 2 patients declined to provide written informed consent. So total 26 patients of malignancy were enrolled in Group A whereas 25 apparent healthy volunteers were observed in Group B ([Figure 1](#)).

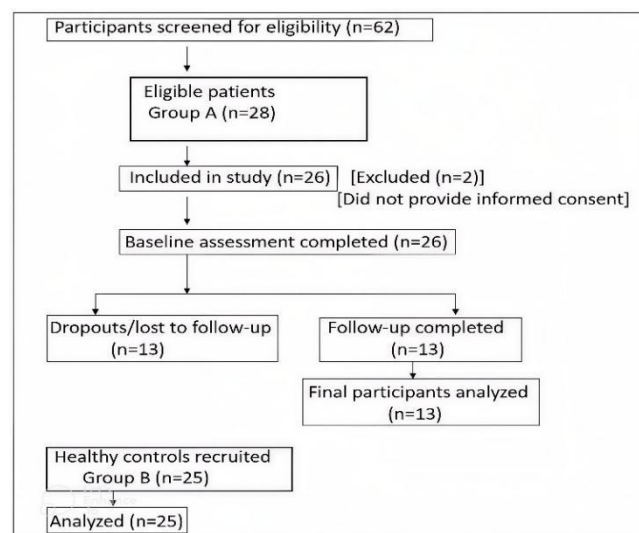


Figure 1: Participant flow diagram.

Out of 26 enrolled patients, maximum i.e. 22 (84.61%) patients were of head and neck cancer, one patient each was of Ca Breast and Thymoma (3.85% each) and 2 (7.70%) patients were suffering from cervix cancer. The study primarily aimed to observe the prognostic pattern among malignancy patients rather than the comparison among the different cancer types however, possible influence of cancer type on observation is acknowledged as a limitation of the study. Follow up assessments were done in three-time intervals, before starting the therapy(baseline), very next day after completion

of the therapy and one month after completion of the therapy. The duration of follow up varied depending up on the treatment schedule of individual participants. Among the enrolled patients, 13 patients completed 3 follow ups in Group A, and rest 13 patients dropped out before 2nd and 3rd follow-up. Five deaths were documented among patients who left the study in between (n = 13). The dropouts were primarily due to disease severity or personal reasons. Only participants with available observations were included in the final analysis; therefore, no missing data were observed among the analyzed cases.

All 100% subjects enrolled in healthy volunteer group had circular shape and uniform spreading of oil drop. ([Table 1](#))

Even though classical texts mention different shapes and directions for both good and bad prognosis, for the purpose of uniformity and statistical analysis the observed outcomes were operationally categorized in to circular and irregular shape and uniform and non-uniform direction. Patterns showing a well-defined, symmetrical, and approximately round spread of oil were categorized as circular, whereas patterns showing asymmetrical, distorted or uneven edges were categorized as irregular. In the same way, if the oil is spreading equally in all directions or consistently along a single direction was considered uniform & diagonal or bidirectional spread of oil drop was categorized as non-uniform.

In malignancy patients at baseline, the ECOG performance scale ranged from 1 to 3, with maximum number of patients with ECOG score 1 (n=20) followed by ECOG 2 (n=5) and ECOG 3 (n=1). Following treatments, functional status improvement was observed and during first and second follow up, only ECOG score 0 & 1 were noted with 3 patients with ECOG 0 and 10 patients with ECOG 1. Correspondingly, *Tailabindu Pareeksha* showed irregular shape (61.54%) followed by circular shape (38.46%) in baseline. A progressive increase in number of circular shapes after oil-drop spreading was observed over successive follow-ups, rising from 61.54% at the first follow-up to 69.23% at the second follow-up. Correspondingly, irregular

morphology decreased from 38.46% to 30.77%. Similarly, uniform spread of oil drop increased from 38.46% at baseline to 61.54% and 69.23% at the first and second follow ups, respectively. Some of the pictures of circular and irregular shapes are given in [Figure 2](#).

Comparison of oil drop shape, direction and ECOG scale:

At baseline in malignancy patients (n=26), circular and irregular oil-drop patterns showed a significant association with ECOG performance status (p=0.007) ([Table 2](#)), and the direction of oil-drop spread (uniform vs non-uniform) was also statistically significant (p=0.019) ([Table 3](#)) During the first follow-up (n=13), both shape of oil drop and direction of oil drop spreading had shown non-significant result (p=0.131), in patients with ECOG 1 and 0 ([Table 4](#), [Table 5](#)). In the second follow-up (n=13), the association between ECOG score and oil-drop shape was not statistically significant (p=0.077) ([Table 6](#)), while the direction of spreading showed a significant association with ECOG score (p=0.027) ([Table 7](#)).

The findings from *Tailabindu Pareeksha* at baseline were maintained in 13 patients lost by means of physical follow-up. About three months after completion of the initial study date, telephonic follow-up was undertaken to assess the clinical status of the patients. Results obtained after treatment were compared with the baseline *Tailabindu Pareeksha* results and the ECOG score of the first assessment ([Table 8](#)). A comparison of baseline socio-demographic characters, clinical characteristics and *Tailabindu Pareeksha* outcomes were performed between patients who completed the study (n = 13) and those who dropped out (n = 13). Both groups demonstrated high homogeneity across all evaluated parameters, as indicated by non-significant results (p> 0.05) ([Table 9](#)).

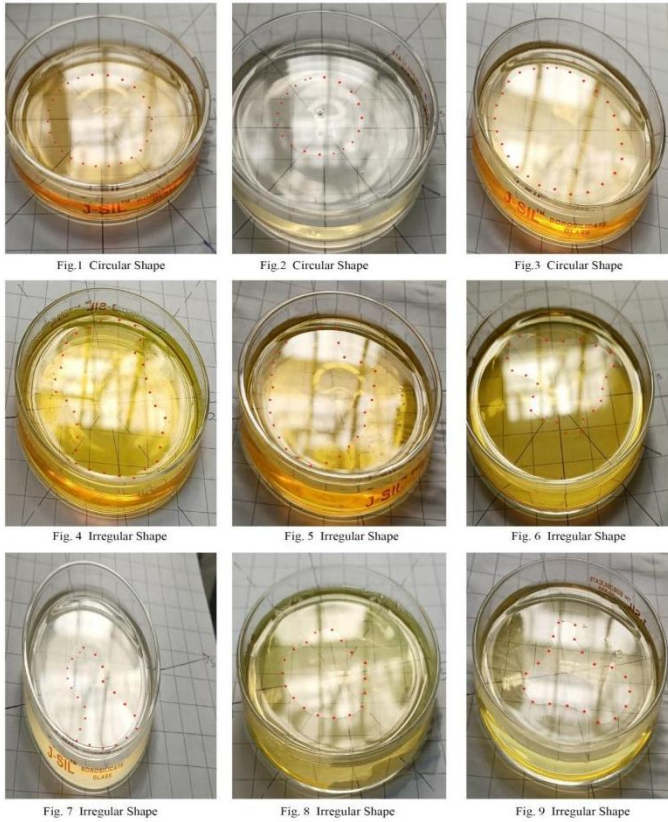


Figure 2: Some of the circular and irregular shapes found during Tailabindu Pareeksha

Table 1: Shape and direction of oil drop in healthy individuals (n=25)

Shape of oil drop	No of patients	Percentage (%)
Circular shape	25	100
Irregular shape	00	00
Uniform spreading	25	100
Non uniform spreading	00	00

Table 2: Association of oil drop shape with ECOG scale during baseline assessment. (n=26)

ECOG	Shape of Oil Drop		Chi square	p	Remark
	Circular	Irregular			
1 (n=20)	7	13	12.028	0.007	S
2 (n=5)	2	3			
3 (n=01)	0	1			

Table 3: Association of oil drop spreading direction with ECOG scale during baseline assessment (n=26)

ECOG	Direction for Spreading		Chi Square	P	Remark
	Uniform	Non-Uniform			
1 (n=20)	13	7	10.000	0.019	S
2 (n=5)	3	2			
3 (n=1)	1	0			

Table 4: Association of oil drop shape with ECOG scale during first follow up (n=13)

ECOG	Shape of Oil Drop		Chi Square	P	Remark
	Circular	Irregular			
0 (n=3)	2	1	2.286	0.131	NS
1(n=10)	6	4			

Table 5: Association of oil drop spreading direction with ECOG scale during first follow up (n=13)

ECOG	Direction for Spreading		Chi Square	P	Remark
	Uniform	Non-Uniform			
0 (n=3)	2	1	2.286	0.131	NS
1(n=10)	6	4			

Table 6: Association of oil drop shape with ECOG scale during second follow up (n=13)

ECOG	Shape of Oil Drop		Chi Square	P	Remark
	Uniform	Non-Uniform			
0 (n=3)	2	1	3.125	0.077	NS
1(n=10)	7	3			

Table 7: Association of oil drop spreading direction with ECOG scale during second follow up (n=13)

ECOG	Direction for Spreading		Chi Square	P	Remark
	Circular	Irregular			
0 (n=3)	2	1	4.900	0.027	S
1(n=10)	9	1			

Table 8: Initial assessment and outcome of left out patients (n=13)

Patient registration No	ECOG Score	Shape	Direction	Condition of patient (as per telephonic conversation)
12	I	Circular	Equal spread	Asymptomatic
17	I	Circular	Equal spread	Asymptomatic
25	I	Circular	Equal spread	Asymptomatic
26	I	Circular	Equal spread	Asymptomatic
11	I	Circular	Equal spread	Asymptomatic
13	II	Irregular	NE	Stable
19	I	Irregular	Equal spread	Symptomatic
20	III	Irregular	West	Symptomatic
3	I	Shira/Irregular	NE	Died
8	I	Irregular	NW	Died
4	I	Irregular	SE	Died
14	II	Irregular	North	Died
15	II	Irregular	SW	Died

Table 9: Comparison of Baseline Characteristics Between Completed and Lost-to-follow-up Participants.

Parameter / Variable	Category	Completed Group (n = 13)	Lost-to- follow-up Group (n = 13)	Statistical Test Used	p-value	Significance
Baseline Socio-Demographic Characteristics						
Age (Years) (Mean ± SD)		50.08 ± 10.97	51.77 ± 9.47	Independent t-test	0.675	NS
Gender	Male	10	8	Chi-square test	0.671	NS
	Female	3	5			
Residential Area	Rural	4	8	Chi-square test	0.238	NS
	Urban	9	5			
Baseline Clinical Characteristics						
ECOG Performance Status	Score 1	12	8	Chi-square test	0.165	NS
	Score 2	1	4			
	Score 3	0	1			
Baseline <i>Tailabindu Pareeksha</i> Parameters						
Shape of Drop	Circular	5	6	Chi-square test	1.000	NS
	Irregular	8	7			
Direction of Spreading	Uniform	10	10	Chi-square test	0.642	NS
	Non-uniform	3	3			

4. DISCUSSION:

At the time of registration, although the subjects in the study were having minimum ECOG score one (i.e. restricted in

physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature. For example, light housework, office work) to maximum 3 (i.e.; capable of only

limited self-care, confined to bed or chair more than 50 % of working hours), their *Tailabindu Pareeksha* reflected this functional impairment. Specifically, 17 subjects showed irregular shape and 9 showed non-uniform spreading. The statistically significant value (pattern, $p=0.007$ & direction $p=0.019$) ([Table 2&3](#)) for baseline evaluation shows that there is some inter-relationship between body pathophysiology with oil drop pattern and direction of spread of oil drop. However, this association did not remain statistically significant during the first follow-up ([Table 4&5](#)) but, during second follow up the direction of spread of oil drop showed a significant association ([Table 6&7](#)). The reduced number of subjects exhibiting irregular patterns and non-uniform spreading at follow-up may be a contributing factor for the variation in statistical significance. At the time of first follow up, i.e. just after completion of radiation / chemo therapy, the health condition of the patient might be questionable because of possible damage to some of the normal cells of concern. Further adverse event occurrence because of chemotherapy also affects person's body general condition negatively So the recovery from the cancer after radiation or chemo therapy won't be much visible in the patient during that time. In second follow up i.e. one month after completion of treatment, there were considerable changes in output. This could be related to the recovery and repair of normal cells following chemotherapy/radiotherapy, as many treatment-related side effects tend to improve after completion of therapy. [15] However, the extent and duration of recovery may vary depending on treatment-related and patient-related factors. A follow-up interval of one month was selected as a standard follow up period to assess early post-treatment changes. While recovery after chemotherapy/radiotherapy can vary depending on various clinical and therapeutic factors, a uniform follow-up duration was maintained for consistency in evaluation. During the first and second follow-up assessments, several patients demonstrated reduction in ECOG scores, suggesting possible

improvement in functional status. A similar pattern was reflected in *Tailabindu Pareeksha*, where increased circular shape and uniform spreading direction were observed during the first follow-up compared to baseline and during the second follow-up compared to the first follow-up. However, statistically significant association was observed only during the second follow-up.

Additional prognostic insights were obtained by telephonic follow-up of 13 patients who were lost to in-person evaluation ([Table 8](#)). Majority of these patients had circular oil drop shape with uniform spreading direction at baseline, and all remained asymptomatic at follow-up, indicating a relatively stable clinical course. Five deaths were reported among the left out 13 patients (These patients died during the course of therapy prior to first follow up assessment). Four patients had an irregular oil drop shape and non-uniform directional spread at baseline, whereas one patient had irregular shape only. Notably, the ECOG score of this patient ranged between 1 and 2, suggesting relatively preserved functional status in this patient despite the unfavorable outcome. This finding indicates, the prognosis was not always correctly based on functional assessment alone. Overall, except for one case, the baseline *Tailabindu Pareeksha* findings were largely in agreement with the clinical status of the patients. Irregular shape and non-uniform oil drop spread appeared to be more frequently associated with adverse outcomes, including symptomatic progression and mortality. From the second follow up as well as from this telephonic update we can assume that the direction of oil drop spreading may reflect the functional changes earlier or more effectively than shape of oil drop. The combined assessment of oil drop shape and spreading direction may potentially also be prognostic. In cases where both parameters showed unfavorable characteristics (irregular shape & non uniform spreading direction), the clinical outcome was consistently negative. Even when only one of the parameters showed adverse prognostic features, unfavorable outcomes were still

observed in some cases. In contrast, circular shape and uniform spreading direction were associated with a better prognosis. The combination of both shape and direction of spread may give prognostic signals better than either parameter alone. All the healthy volunteers exhibited circular shape and uniform spreading of oil drop ([Table 1](#)) ([Figure 2](#)), which corresponded to good prognostic features described in ayurvedic texts and supports the observation mentioned in classical text statement. This consonance between textual descriptions and observations in healthy individuals offers preliminary support for the traditional principles of *Tailabindu Pareeksha*.

A small proportion of patients had comorbidities including diabetes mellitus, hypertension, and ischemic heart disease, while the majority (84.61%) had no comorbidities. Notably, none of the patients who died during the treatment period had these recorded comorbidities. Separate analysis regarding the effect of these conditions on study findings was not performed due to limited sample size.

The shape of the oil drop after spreading is depends on the surface-active molecules that are present in different amounts on the surface of urine. The different shapes reflect biochemical variations influencing surface tension and interfacial tension between urine and oil. Surface tension of body fluids has a correlation in developing pathological states.[16] The spreading behavior of oil on the urine surface is primarily influenced by the surface tension of urine, which in turn depends on its chemical composition. The surface tension of urine becomes lower when it contains high amounts of organic or oily substances including lipids and proteins and bile pigments. As a result, the oil drop spreads more widely over the surface. Urinary constituents such as bile salt and sodium chloride can influence urine surface tension, [10,16] which in turn can influence the oil drop spreading pattern. The surface tension of oil becomes disrupted by surfactant-like molecules which include bile salts and specific proteins and metabolites leading to irregular oil spreading and broken uneven margins. The

different oil spread patterns reveal biochemical changes in urine which help identify shifts in metabolic processes. If there is any irregularity in the pattern or amount of such constituents that may leads to the irregular spreading of oil drop and thus forming irregular shapes. In each disease there might be changes in this molecule and that is the reason for getting different shapes in different diseases. These molecules may be traces in amount but affect the urine properties very much thus are a very good or important indicator for the pathological conditions. [17] In this study urine routine investigations such as pH, specific gravity, protein, glucose and microscopic evaluations were done. Although specific gravity was not measured, these physiochemical parameters might influence the oil drop spreading. However, the direct correlation between urine biochemical parameters and oil drop spreading patterns was not evaluated in the present study. In classics while explaining the *Asadhya* shapes of oil after spread, there is mentioning of *Gatrakhanda* or other irregular shape. [18] these all are indication of bad prognosis. In this study, those patients died during study had such shapes which is a clear indicative of *Asadhya Avastha*. Their direction of spread was EN, NW, ES, SW, and North respectively. Spread of oil drop towards *Eshana*, *Agneya*, *Nairutya*, *Vayavya* are considered to indicate poor prognosis. [19] Patterns of irregular shapes are shown in [Figure 2](#). In the present study, patients exhibited such patterns in *Tailabindu Pareeksha* died during the treatment course which may support the classical reference. However, definitive conclusions cannot be made due to limited sample size and possible confounding factors such as disease severity, treatment variability and patient's clinical condition.

Since there is more drop out in the present study, comparison of baseline properties of both completed and dropout patients are essential ([Table 9](#)), the statistical analysis demonstrates complete baseline homogeneity between the groups. No significant differences were observed in demographic traits, clinical characteristics and *Tailabindu Pareeksha* outcomes.

These findings strongly confirm that patient dropouts occurred entirely at random and did not skew the prognostic observations of the study.

The findings of the present study should be interpreted cautiously due to the limited sample size and clinical heterogeneity among participants. Therefore, generalizability of the observations to larger or different patient populations remains limited. Further large-scale studies are required to validate the prognostic utility of *Tailabindu Pareeksha*. The findings of *Tailabindu Pareeksha* showed correlation with ECOG Performance Status in several patients. Although ECOG Performance Status was used as a clinically accepted comparator for prognostic assessment, it primarily evaluates the functional status of patients. Hence, further validation of *Tailabindu Pareeksha* findings using more comprehensive prognostic outcome measures may be necessary.

One of the aims of study was to build a mathematical model to correlate with dependent variable and to predict the experimental outcomes. Data were taken from 26

malignant patients and 25 healthy volunteers, totaling 51 subjects. A *Tailabindu Pareeksha* was performed that recorded four dependent variables, namely Shape of oil drop, Direction of spread, Time for complete spread, Area covered (number of blocks). The independent variable was class (malignant/control). Using MATLAB curve fitting toolbox (interpolant, linear method with scaling and auto-fit), various variable combinations were tested to evaluate prediction accuracy via R^2 values. It was found to be, Direction & blocks: 68% accuracy, spreading time & shape: 73%, Direction & shape: 57%, Direction & spreading time: 82%, Shape & blocks: 76%, Spreading time & blocks: 100% accuracy. From this it is also understood that, when the dependent variables are both numerical values, the result will be more accurate. If one value is numerical and other is a subjective one then there will be reduction in accuracy. The graphical representation of the model is shown in [figure 3](#). From this model one can easily distinguish the class (here malignant and control).

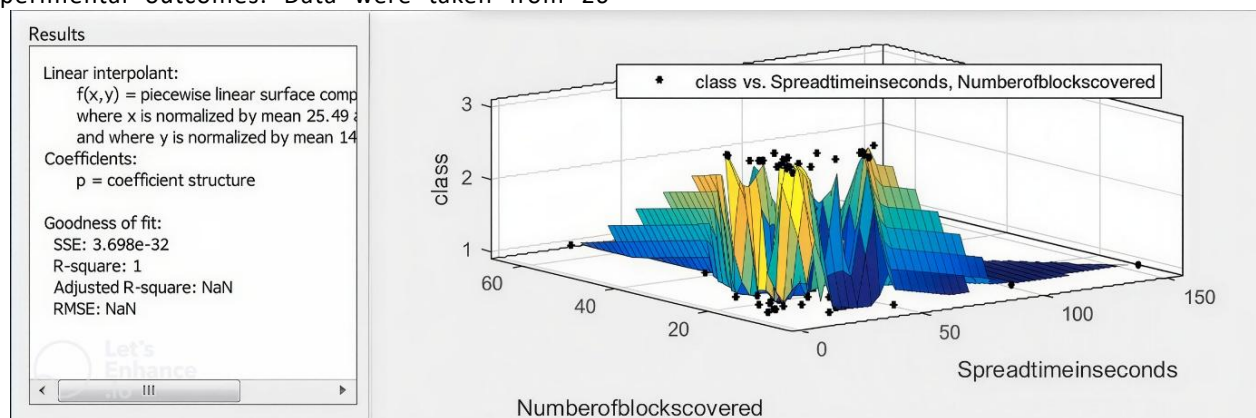


Figure 3: Accuracy prediction model with spreading time and number of blocks covered as depended variables.

The observed R^2 value of 1 for the area versus time feature combination may indicate strong apparent separation within the present dataset. But considering the limited sample size, the possibility of overfitting cannot be excluded. So, further studies employing larger datasets and advanced machine learning approaches are planned to evaluate model generalizability, feature-selection influence,

overfitting/underfitting behavior, and the apparent absence of noise in the current dataset.

Limitations:

Although our results are encouraging, a relatively high attrition rate was observed during follow-up, which may have affected the robustness, generalizability and statistical power of the results. The study population included heterogeneous malignancies with vary in treatment modalities, disease

characteristics, and clinical conditions, which could have influenced the observed *Tailabindu Pareeksha* patterns. The potential influence of associated comorbidities on prognostic findings was not analyzed separately. Although routine urine investigations were performed, direct correlation between urine biochemical parameters and oil drop spreading patterns was not evaluated. One of the important urine parameter surface tension was also not assessed. Furthermore, confidence intervals, effect size estimation, predictive accuracy metrics, multivariable adjusted analyses, and advanced statistical handling of dropout cases were not performed due to the exploratory nature of the study and limited sample size. In addition, the follow-up duration was relatively short. Formal matching between malignancy patients and healthy volunteers were also not done in this present study. Another important limitation is the absence of a universally accepted gold-standard prognostic assessment tool for direct comparison with *Tailabindu Pareeksha*, which limits comprehensive evaluation of its prognostic accuracy and clinical applicability.

5. CONCLUSION:

This pilot observational study suggests that *Tailabindu Pareeksha* may be associated with the changes in scores of ECOG among malignancy patients, indicating its potential as a simple, non-invasive prognostic assessment tool. However due to the pilot nature of the study, limited sample size, participant dropout during follow up and heterogeneity of malignancies, the result should be interpreted cautiously. Larger prospective studies with adequate sample size, longer follow up duration, comprehensive statistical analysis, and comparison with established prognostic indicators are required to further validate its prognostic applicability in malignancy.

Key message: Overall, *Tailabindu Pareeksha* shows preliminary evidence as a simple, non-invasive prognostic assessment tool in malignancy; but its clinical utility requires validation in larger prospective studies before clinical application.

ABBREVIATIONS

ECOG - Eastern Cooperative Oncology Group; Chi square – Chi square value

p – probability value; SD: Standard Deviation; S – Significant

NS – Not significant; NE – North east; NW – North west; SE – South east

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