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A Comparative Clinical Study Of *Tail Dhara* And *Takra Dhara* In The Management of *Anidra* w.s.r To Insomnia

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ABSTRACT: -

Background:-The impact of insomnia is far reaching and may affect both physical and emotional health as well as intellectual capacity. Understanding the potential causes of sleep disruption and the range of possible solutions will allow many to overcome the difficulty of disrupted sleep. The present study was undertaken to evaluate the efficacy of *Tail Dhara* with *Karpasasthyadi Tail* and *Takra Dhara* with medicated *Takra* (Butter milk) in *Anidra* (Insomnia) before and after treatment in Group A and Group B.

Material and Methods:A sample size of 20, diagnosed cases of *Anidra* (Insomnia) were selected from the O.P.D &I.P.D of Shree Shivayogeeshwara Rural Ayurvedic Medical college & hospital Inchal, camps and other referrals.

Results: Results obtained after the clinical trial was analyzed statistically and all the observations were subjected to creative discussions. Groups B showed significant result when statistically compared before and after the treatment with Group A, and when comparison between the two groups were done to know which, one is better compared to the other, it was shown statistically and clinically significant.

Conclusion: Both the procedures were studied statistically, the results obtained by statistically both the groups have equal effect on Insomnia but clinically *Taila Dhara* is having slightly better result than *Takra dhara.*

Key word- *Nidra ,Shirodhara ,Insomnia,Tail Dhara ,Takra Dhara*

INTRODUCTION

Insomnia is among the most common health complaints in medical practice and most prevalent of all sleep disorders.[1] In this modern era also called "Era of Anxiety and stress", *Nidra* (sleep) is the most common neglected part of life where one gives least importance to the timing, duration and quality of sleep with stress playing an important role in inducing Insomnia. This negligence leads to *Vataprakopa* and in turn causing various physical and psychiatric illnesses. Sleep is sensitive to disturbances by many internal influences, such as excessive worry, excessive anxiety and a depressed mood. Sleep can also be disturbed by many external influences, for example, transient stress, an important life event, excessive noise, high or low room temperature, an uncomfortable bed, unfamiliar surroundings & drug withdrawal.[2] Several types of etiological factors can cause chronic difficulty sleeping, including circadian rhythm disorders, psychiatric disorders, physical illness, sleep related physiological disorders and negative conditioning effects. Recent studies have shown that about 40% of women and 30% of men are suffering from Insomnia. Population studies have revealed that 10 to 18% of adults considered sleep to be a serious chronic problem with higher prevalence problem in women and elderly. In 1/3rd population of the world suffering from various sleep disorders out of which 10 to 20 % belongs to Insomnia.[3]

The four factors are portrayed as common etiological and precipitating factors for episodes of Insomnia. They are:

Circadian factors:

- Disturbances of the circadian rhythm such as shift work, jet lag & Sleep scheduling can cause inability to sleep.

- Poor sleep hygiene Eg. Noise

Psychiatric factors:[4]

- Mental disorders such as clinical depression, generalized anxiety disorder, post-traumatic stress, Schizophrenia or Obsessive-compulsive Disorders.
- Psychiatric drugs or stimulants including certain medications like amphetamines etc.,
- Life problems like fear, stress, anxiety, emotional or mental tension, work problems, financial stress etc.,
- Parasomnia which includes a number of disruptive sleep events including nightmares, sleep walking, violent behavior etc.,

Pharmacological factors: β –blockers corticosteroids Broncho dilators (Eg. Metaproterenol)
Respiratory stimulants (eg.Theophylline) Stimulating antidepressants (Eg. Protriptyline, fluoxetine, buproprionetc.,) Methyldop, Thyroid supplements Central Nervous system stimulants Decongestants Phenytoin

Sapeksha Nidana **(Differential Diagnosis)**
Sapeksha nidana for *Nidranasha* (Insomnia) cannot be explained but *nidranasha* (Insomnia) is seen as a *laksana* (Symptoms) in various disorders like: *Vatajajwara, Pittajajwara,*

Sannipatajajwara, Vatapittajajwara, Atisara, Vataarshas, Viryakshaya, Visuchika, Tamakaswasa, Apasmar, Karnavedana, Shiroroga, Kshaya.[5]

MATERIAL AND METHODS

This is a comparative clinical study of *Takra Dhara & Taila Dhara* conducted on Insomnia. As per the inclusion and exclusion criteria's, patients of Insomnia were selected randomly. A total of 40 patients, 20 in each group with 4 dropouts were registered for the study. Patients of Group A underwent *Takra Dhara*, while the patients of Group B received *Taila Dhara (Karsasthyadi Tail)* for duration of 8 days. The symptoms assessment was done daily before & after the treatment but symptoms was observed from 1st day & on the 8th day.

Research Design: A Randomized Comparative Clinical study

Diagnostic Criteria:

- For diagnosis detailed medical history will be taken and physical examination will be done according to both Ayurvedic and modern clinical methods.
- To assess the psychological intactness, mental status examination will be carried out.
- To confirm or to exclude the other medical disorders routine hematological and urine investigations will be carried out.
- Below said guidelines mentioned in ICD-10 will be followed.[6]

a) A complaint of difficulty falling asleep, maintaining sleep, or non-refreshing sleep.

b) The sleep disturbance occurs at least three times per week for at least one month.

c) The sleep disturbance results in marked personal distress or interference with personal functioning in daily living.

d) Absence of any known causative organic factor, such as neurological or other medical condition, psychoactive substance use disorder or a medication

e) Sleep efficacy index (SEI)was calculated to support the diagnosis with the help of formula

$$SEI = \frac{TOTAL\ SLEEP\ TIME}{TIME\ IN\ BED} \times 100$$

SEI- Is expressed as a percentage % an index of less than 80% indicate poor sleep

Inclusion Criteria:

- Chronicity up to 5 years.
- Age group between 25-60 years.
- Patients of either sex, irrespective of socio-economic status.
- Patients ready to sign informed consent form.
- Patients of mild hypertension

Exclusion Criteria:

- Patients with moderate and severe hypertension and hypotension.
- Any other systemic disorders and psychiatric disorders where insomnia is found secondary to that.
- *Nidranasha* (Insomnia) due to *Madatyaya*(Alcoholism) */ Abhighata* (Injury).
- Patients under hypnotic medications or other drugs which are known to cause drowsiness.
  Physiological conditions like pregnancy, lactation and puerperal stage.

SAMPLE SIZE –

a. Group A- A minimum of 20 patients fulfilling the diagnostic and inclusion criteria were treated with *Karpasthyadi Tail Dhara*

b. Group B- A minimum of 20 patients fulfilling the diagnostic and inclusion criteria were treated with The *Takra* (Buttermilk) *& Amalaki Kashaya.*

ASSESSMENT CRITERIA

Assessment was done by considering the base line of data of subjective and objective parameters to pre and post medication, compared for assessment of result and were analyzed statistically with appropriate test

OBSERVATION PERIOD -Initially on the first day before treatment. On the 8th day after treatment.

Follow up – In both groups follow up was done on 14th day, and 21th day.

Statistical Method- It was an Observational clinical study with pre and posttest design. The patients were assigned to two group and were administered *tail dhara* and *takra dhara*. The results were analyzed statistically. Statistical Analysis was done using Chi- Square test, Mann Whitney u test and Wilcoxon matched paired test

OBSERVATIONS & RESULTS

Analysis of treatment effects of *Karpasthtyadi Taildhara* in Group-A and *Takradhara* in Group –B.

Effects Of *Karpasthyadi Tail Dhara* (Group-A)
Table No.01. Effect Of Group-A On ASI

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
ASI	Pretest	16.65	2.16	16.00	2.75	30.50	-5.4100	0.0001 *
	Posttest	9.25	2.65	9.50	3.75	28.90	-4.5444	0.0001 *

Effect of *Takradhara* (Group-B)
Table.No.02. Effect of Group-B on ASI

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
ASI	Pretest	5.30	3.74	5.00	6.00	10.50	-5.4100	0.0001 *
	Posttest	2.90	3.14	2.00	3.50	12.10	-4.5444	0.0001 *

EFFECT ON Sleep Induction
Table.No.03 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Sleep induction	Pretest	2.75	0.44	3.00	0.75	30.38	-5.3424	0.0001*
	Posttest	1.25	0.44	1.00	0.75	27.38	-3.7194	0.0002*

EFFECT ON Sleep Induction
Table.No.04 Effect of Group B

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Sleep induction	Pretest	0.65	0.59	1.00	1.00	10.63	-5.3424	0.0001*
	Posttest	0.40	0.60	0.00	1.00	13.63	-3.7194	0.0002*

EFFECT ON Awakening During Night
Table.No.05 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Awakening during night	Pretest	2.90	0.45	3.00	0.00	28.65	-4.4092	0.0001*
	Posttest	1.55	0.94	2.00	1.00	26.68	-3.3407	0.0008*

EFFECT ON Awakening During Night
Table.No.06 Effect of Group B

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Awakening during night	Pretest	1.00	1.12	1.00	2.00	12.35	-4.4092	0.0001*
	Posttest	0.45	0.83	0.00	1.00	14.33	-3.3407	0.0008*

EFFECT On Final Awakening Earlier Than Desire
Table.No.7 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Final awakening earlier than desired	Pretest	2.95	0.22	3.00	0.00	29.33	-4.7743	0.0001*
	Posttest	1.70	0.66	2.00	1.00	28.20	-4.1657	0.0001*

EFFECT On Final Awakening Earlier Than Desire
Table.No.8 Effect of Group B

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Final awakening earlier than desired	Pretest	1.15	0.99	1.00	2.00	11.68	-4.7743	0.0001*
	Posttest	0.50	0.61	0.00	1.00	12.80	-4.1657	0.0001*

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EFFECT On Overall Quality Of Sleep
Table.No.9 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Overall quality of sleep	Pretest	1.00	0.00	1.00	0.00	24.50	-2.1640	0.0305*
	Posttest	0.95	0.22	1.00	0.00	25.50	-2.7050	0.0068*

EFFECT On Overall Quality Of Sleep
Table.No.10 Effect of Group B

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Overall quality of sleep	Pretest	0.60	0.50	1.00	1.00	16.50	-2.1640	0.0305 *
	Posttest	0.45	0.51	0.00	1.00	15.50	-2.7050	0.0068 *

EFFECT On Sense Of Well being During day
Table.No.11 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Sense of well being during day	Pretest	0.85	1.31	0.00	2.50	23.25	-1.4878	0.1368
	Posttest	0.20	0.62	0.00	0.00	21.05	-0.2976	0.7660

EFFECT On Sense Of Well being During day
Table.No.12 Effect of Group B

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Sense of well being during day	Pretest	0.10	0.31	0.00	0.00	17.75	-1.4878	0.1368
	Posttest	0.05	0.22	0.00	0.00	19.95	-0.2976	0.7660

EFFECT On Functioning During Day
Table.No.13 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Functioning (physical and mental)during day	Pretest	2.40	0.94	3.00	1.00	27.95	-4.0305	0.0001 *
	Posttest	1.40	0.82	1.50	1.00	25.80	-2.8673	0.0041 *

EFFECT On Functioning During Day
Table.No.14 Effect of Group A

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Functioning (physical and mental)during day	Pretest	0.80	0.83	1.00	1.00	13.05	-4.0305	0.0001 *
	Posttest	0.55	0.89	0.00	1.00	15.20	-2.8673	0.0041 *

EFFECT On Sleepiness During Day
Table.No.15 Effect of Group A

Variables	Time	Group A					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Sleepiness during the day								
	Pretest	0.65	0.59	1.00	1.00	18.90	-0.3508	0.7257
	Posttest	0.70	0.66	1.00	1.00	25.15	-2.5157	0.0119 *

EFFECT On Sleepiness During Day
Table.No.16 Effect of Group B

Variables	Time	Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank		
Sleepiness during the day								
	Pretest	0.72	0.57	1.00	1.00	20.17	-0.3508	0.7257
	Posttest	0.15	0.37	0.00	0.00	15.85	-2.5157	0.0119*

Assessment Of Total Effect Of Therapy

Table:17- Comparison Of Pretest And Posttest Athens Insomnia And Its Components Scores In Group A By Wilcoxon Matched Pairs Test

Variables	Time	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
ASI	Pretest	16.65	2.16					
	Posttest	9.25	2.65	7.40	2.68	44.44	3.9199	0.0001*
Sleep induction	Pretest	2.75	0.44					
	Posttest	1.25	0.44	1.50	0.51	54.55	3.9199	0.0001*
Awakening during night	Pretest	2.90	0.45					
	Posttest	1.55	0.94	1.35	0.88	46.55	3.6214	0.0003*
Final awakening earlier than desired	Pretest	2.95	0.22					
	Posttest	1.70	0.66	1.25	0.55	42.37	3.8230	0.0001*
Total sleep duration	Pretest	3.00	0.00					
	Posttest	1.50	0.95	1.50	0.95	50.00	3.7236	0.0002*
Overall quality of sleep	Pretest	1.00	0.00					
	Posttest	0.95	0.22	0.05	0.22	5.00	0.0000	1.0000
Sense of well being during day	Pretest	0.85	1.31					
	Posttest	0.20	0.62	0.65	1.09	76.47	2.3664	0.0180*
Functioning (physical and mental)during day	Pretest	2.40	0.94					
	Posttest	1.40	0.82	1.00	0.79	41.67	3.3137	0.0009*
Sleepiness during the day	Pretest	0.65	0.59					
	Posttest	0.70	0.66	-0.05	0.83	-7.69	0.2548	0.7989

*p<0.05

Table:18- Comparison of pretest and posttest ATHENS INSOMNIA and its components scores in group B by Wilcoxon matched pairs test

Variables	Time	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
ASI	Pretest	5.30	3.74					
	Posttest	2.90	3.14	2.40	4.02	45.28	2.7813	0.0054*
Sleep induction	Pretest	0.65	0.59					
	Posttest	0.40	0.60	0.25	0.44	38.46	2.0226	0.0431*
Awakening during night	Pretest	1.00	1.12					
	Posttest	0.45	0.83	0.55	0.76	55.00	2.5205	0.0117*
Final awakening earlier than desired	Pretest	1.15	0.99					
	Posttest	0.50	0.61	0.65	0.75	56.52	2.8031	0.0051*
Total sleep duration	Pretest	1.05	1.05					
	Posttest	0.35	0.81	0.70	0.86	66.67	2.8031	0.0051*
Overall quality of sleep	Pretest	0.60	0.50					
	Posttest	0.45	0.51	0.15	0.37	25.00	1.6036	0.1088
Sense of well being during day	Pretest	0.10	0.31					
	Posttest	0.05	0.22	0.05	0.22	50.00	0.0036	1.0000
Functioning (physical and mental)during day	Pretest	0.80	0.83					
	Posttest	0.55	0.89	0.25	0.44	31.25	2.0226	0.0431*
Sleepiness during the day	Pretest	0.70	0.57					
	Posttest	0.15	0.37	0.55	0.83	78.57	2.2752	0.0229*

*p<0.05

Table:19 Comparison of two study groups (A and B) with pretest and posttest ATHENS INSOMNIA and its components scores by Mann-Whitney U test

Variables	Time	Group A					Group B					Z-value	p-value
		Mean	SD	Median	IQR	Mean rank	Mean	SD	Median	IQR	Mean rank		
ASI	Pretest	16.65	2.16	16.00	2.75	30.50	5.30	3.74	5.00	6.00	10.50	-5.4100	0.0001*
	Posttest	9.25	2.65	9.50	3.75	28.90	2.90	3.14	2.00	3.50	12.10	-4.5444	0.0001*
Sleep induction	Pretest	2.75	0.44	3.00	0.75	30.38	0.65	0.59	1.00	1.00	10.63	-5.3424	0.0001*
	Posttest	1.25	0.44	1.00	0.75	27.38	0.40	0.60	0.00	1.00	13.63	-3.7194	0.0002*
Awakening during night	Pretest	2.90	0.45	3.00	0.00	28.65	1.00	1.12	1.00	2.00	12.35	-4.4092	0.0001*
	Posttest	1.55	0.94	2.00	1.00	26.68	0.45	0.83	0.00	1.00	14.33	-3.3407	0.0008*
Final awakening earlier than desired	Pretest	2.95	0.22	3.00	0.00	29.33	1.15	0.99	1.00	2.00	11.68	-4.7743	0.0001*
	Posttest	1.70	0.66	2.00	1.00	28.20	0.50	0.61	0.00	1.00	12.80	-4.1657	0.0001*
Total sleep duration	Pretest	3.00	0.00	3.00	0.00	29.50	1.05	1.05	1.00	2.00	11.50	-4.8690	0.0001*
	Posttest	1.50	0.95	2.00	1.00	26.70	0.35	0.81	0.00	0.00	14.30	-3.3542	0.0008*
Overall quality of sleep	Pretest	1.00	0.00	1.00	0.00	24.50	0.60	0.50	1.00	1.00	16.50	-2.1640	0.0305*
	Posttest	0.95	0.22	1.00	0.00	25.50	0.45	0.51	0.00	1.00	15.50	-2.7050	0.0068*
Sense of well being during day	Pretest	0.85	1.31	0.00	2.50	23.25	0.10	0.31	0.00	0.00	17.75	-1.4878	0.1368
	Posttest	0.20	0.62	0.00	0.00	21.05	0.05	0.22	0.00	0.00	19.95	-0.2976	0.7660
Functioning (physical and mental)during day	Pretest	2.40	0.94	3.00	1.00	27.95	0.80	0.83	1.00	1.00	13.05	-4.0305	0.0001*
	Posttest	1.40	0.82	1.50	1.00	25.80	0.55	0.89	0.00	1.00	15.20	-2.8673	0.0041*
Sleepiness during the day	Pretest	0.65	0.59	1.00	1.00	18.90	0.72	0.57	1.00	1.00	20.17	-0.3508	0.7257
	Posttest	0.70	0.66	1.00	1.00	25.15	0.15	0.37	0.00	0.00	15.85	-2.5157	0.0119*

*p<0.05 indicates significant
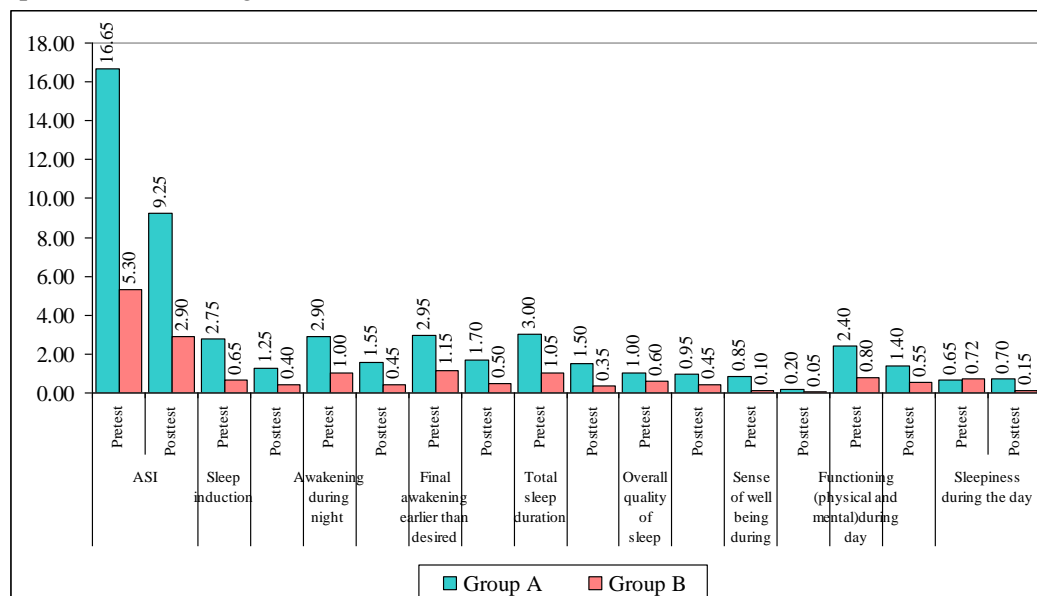
Data Related to Overall Response to Treatment

- In Group A out of 20 patients 2 patient showed marked improvement, 4 patients showed moderate improvement, 7 patients showed mild improvement, and 5 patients registered no change.

- In Group B out of 20 patients 1 patient showed marked improvement, 6 patients showed moderate improvement, 8 patients showed mild improvement, and a total of 3 patients registered no change

- By comparing the overall response for the treatment, it can be concluded that Group B patients responded better than the Group A in case of mild improvement. In case of marked and moderate improvement no. of patients are more in groups B**.**

DISCUSSION

Dhara is a procedure where it is continuously poured over the forehead. *Murdha* (Head) is a place in which manas and prana *Vayu* are situated.[7] Over exposure to psychological stress and strain definitely leads to vitiation of manas and prana *Vayu*. Both in turn lead to pathological condition. By pouring *Dhara* over forehead continuously, the vitiated *Prana Vayu* and manas will be countered and establishes normal functions of manas and *Prana Vayu*, so as the Insomnia. *Agnya Cakra* (midpoint between the eyebrows) is the seat of the pituitary and Thalamus, as pituitary is master gland of endocrine system, which responds to stress, anxiety, etc. via hypothalamus.[8] The hypothalamus sends impulses to the sympathetic division of ANS including adrenal medulla and impacts on cardiac as well as renal systems resulting into vascular resistance and water retention respectively, and leads to increased blood pressure.[8] *Dhara* stimulates the pituitary gland by its penetrating effect. Also, the hypothalamus is influenced; in turn it reduces the impulses of sympathetic division.[9] As a result, the exaggerated contractility of heart reduces, also the systemic vascular resistance. In such circumstances the blood flow to kidneys increases and inhibits the release of renin as well as angiotensin II.[10] As a consequence, the retention of Na+ ions reduce, which ultimately reduces the mild hypertension induced insomnia.

Sympathetic hyperactivity and parasympathetic withdrawal are cause for the

Insomnia. The autonomic imbalance is in turn related to reduced or reset arterial baro reflex sensitivity and chemoreflex induced hyperventilation.[11] The *Dhara* relaxes the mind, body and exaggerated vital functions like heart rate, respiratory rate. This normal state of vital functions increases baro reflex sensitivity and reduces the sympathetic activity and chemoreflex activation. As a result, tension reduces.[12]

Therapeutic effect of medicaments used

Karpasthyadi Tail that is poured on the forehead, enters the circulatory system through the fine pores present over the scalp and forehead, here it is digested by the *Bhrajaka Pitta*. [13]

This Ayurvedic concept is supported by modern medicine which states that it is possible to produce a certain amount of absorption by the application of substances conveyed in fatty vehicles.[14] Looking in to the physiology of absorption. In man percutaneous absorption probably occurs mainly from the surface. The concept of percutaneous absorption is aged in modern physiology depends on, The skin itself. The vehicle affecting the transfer.[15] The substance which permeates or penetrates is absorbed. The barrier to absorption is placed in the stratum granulosum and stratum lucidum, which represents an electric double layer with positive hydrogen ions on the inner side. The dermal appendages however afford a break in the intact epidermis. If a substance penetrates follicular canals and reaches the duct of the sebaceous gland and then the gland cells it has circumvented the absorption barrier.[16] The permeability of the cells of the sebaceous gland is greater than that of the granular layer of the epidermis. The concept that the lining of the epidermis allows the penetration of the cells by lipoid substances is theoretically true.[17]

CONCLUSION

In both the procedures, the results obtained by statistically both the groups have equal effect on Insomnia but clinically *Taila Dhara* is having slightly better result than *Takra dhara*. Additionally, we would like to understand the mechanism of action of *Dhara* using brain functional magnetic resonance imaging and specifically note if a specific area within the brain is getting activated after *Dhara*. Any positive findings from these studies would establish *Dhara* as a noninvasive approach to the management of insomnia.

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