Chapter 6

CLINICAL STUDIES
The method used to evaluate the efficacy of Shoolaghna effect of Panchakol was clinical studies. Clinical study was conducted on 428 patients. Clinical study was conducted in all the three types of Desh i.e. in Sadharan Desh (Pune Dist.), in Anoop Desh (Sindhudurga Dist.) and In Jangal Desh (Yavatmal Dist.)

A) Criteria for Selection of Patients:

The type of selection of patient was Random Selection. Patient having main symptom Shool was the only criteria. Patient of any sex; from any Desh; having age in between 12 years to 70 years; having any Prakanti and any Satwa was taken into consideration. Any type of Shool, may be as a disease or a symptom from any other disease; may be Ashukari (Acute) or Chirakari (Chronic); may be Ekanga (Localised) on Sarvang (Generalised); Satat (Continuous) or Vichchhinna (Intermittent) was taken into consideration.

Age Group : Minimum 12 year maximum 70 yrs.

Exclusion Criteria:

* Age < 12 yrs. And > 70 years
* Patient having acute abdomen i.e. indicated for surgery.
* Pt. having any malignancy.
* Pt. having acute cardiac pains.
* Pt. having active peptic or duodenal ulcer.
* Pregnancy.

B) Criteria for the Severity of Shool: According to severity, Shool was classified into 3 types. Viz. 1) Teevra Shool (Severe pain), ii) Madhyam Shool (Moderate pain). iii) Manda Shool (Mild Pain). The criteria for severity of Shool was decided as follows:

1) Teevra Shool (Severe pain): Any two of following symptoms and signs.
   a) Pt is bed ridden.
   b) Pt is not able to do his normal day to day routine work.
   c) Pt is restless.
   d) Pt cannot concentrate on his routine work.
   e) Change in position and gate.
   f) Non functioning of affected part.
   g) Pt cannot sleep. Insomnia due to severe pain is there.

2) Madhyam Shool (Moderate pain): 
   a) Pt is not in bed and can move here and there.
   b) Pt may able to do his normal routine work if he decided to do so.
   c) Non restless and can concentrate the work.
   d) No change in position or gate.
   e) Dysfunctions of affected part.
1) Pt can sleep but not so sound.

3) *Mand Shool* (Mild Pain):
   a) Pt can move easily here and there.
   b) Pt can do his normal routine work with full concentration easily.
   c) No feeling of pain during engaged in any work but feeling the pain when empty or workless.
   d) Pt can sleep well and soundly.
   e) only pain without any dysfunction of affected part.

Variation in the doses was done according to age Desh Prakruti and Doshapradhanya. 2 gm. to 5 gm. Of *Panchakol churna* was used accordingly (2 gm. To 5 gm. fine powder of *Panchakol* for gr. A and 2 gm. to 5 gm. Coarse powder of *Panchakol* for Gr. B)

*Anupan* : Following *Anupan* was used for Gr. A only according to *Dosh Pradhanya*. For *kapha Pradhanya* hot water, for *Pitta Pradhanya* hot water with 1 tea spoon ghee and for *Vat Pradhanya* hot water with 1 tea spoon castor oil. The treatment was given for 7 days each 3rd, 5th, 7th day follow up of each pt was taken to observe the relief of *Shool*.

*Methods* : The method used to evaluate the efficacy of shoolaghna effect of panchakol was single blind clinical trials with control group. These 428 patients were divided randomly into 3 groups. Viz.

Group A - Treatment group treated with *Panchakol choorna*. 

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Group B - Treatment group treated with panchakol yavagoo.

Group C - Control group treated c plain yavagoo

No other medicine was used. This treatment was given for about seven days. Shool was main criteria for the selection of pt. Shool may be a disease or a main symptom from any other disease was taken into consideration. If the shool was a symptom, then inspite of considering the pathogenesis of that disease, pathogenesis of the shool (i.e. weather it is due to upasthambhit vata or Nirupastambhit vata) was taken into consideration. Each pt was treated for maximum period of 7 days. On each 3rd, 5th, and 7th days follow up of patient was taken to observe the shifting of the severity of shool. On 14th day; Follow up of each pt was again taken to observe any increase on decrease in the severity of shool comparing with follow up of 7th day. In this period i.e.: from 7th day to 14th day no treatment was given. Follow up of 7th day was taken into consideration for results. Upashama was estimated by following method.

Evaluation of Upashama: As shool is subjective symptom it was quite difficult to evaluate the Upasham in shool. To avoid bias and to get maximum accuracy a method-visual analgo scale was adopted. Shool was graded according to severity (criteria of which is discussed previously) as follows:

- Teevra Shool - (severe pain) 4
- Madhyan Shool (Moderate pain) - 3
- Manda Shool (Mild pain) - 2
If the score of Shool after treatment (on 7th day of follow up) (S.A.T.) is subtracted from the score of Shool before treatment (S.B.T.) we can get Upasham. Shifting of this score code towards negative side is upashana. Thus after subtraction remaining number indicates grade of Upashama.

**S.B.T. CODE - S.A.T. Code - Upashama grade.**

- If it is 4: Shool Nivrutti - 100% Upasham.
- 3: Prabhu Upashama - 75% Upasham.
- 2: Madhyam Upashama = 50% Upasham.
- 1: Alpa Upashama = 25% Upasham.
- 0: Anupashama = 0% Upasham.

*E.g.* If S.B.T. is 4 and S.A.T. is 0, then 4-0 = 4 means there is Shool nivrutti. Thus the Upasham in each and every pt was evaluated.

In this manner a clinical study on 428 pts was conducted and collected data was arranged according to Sex, Age, Desh, Prakruti, Satwa, Type of Shool and Upashama.