A SYSTEMIC REVIEW OF VAMAN CLINICAL TRIALS REGISTERED IN CTRI.

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ABSTRACT

Introduction: In Sep 2004, ICMJE (International Commission of Medical Journal Editors) implemented a dramatic and important policy for the condition of publication of clinical trials. The condition was that clinical trials must be registered in a public trial registry. CTRI is the India’s international centralised network of registries and partner registries along with data providers. Specific Shodhan treatment Panchkarmas for the balance of specific Dosha has been advised viz Vaman/Vamana for Kapha, Virechan for Pitta and Basti for Vata Dosha. Vaman/Vamana is a treatment for the Kaphaj Vyadhis mentioned in the ancient texts of Ayurveda. Hence here an attempt has been made to analyse the data of Vaman/Vamana opted for the intervention and / or comparator agent in clinical trials which are registered in CTRI. Objectives: The objective of this study was to collect the data of clinical trials of Vaman/Vamana registered in CTRI and analyse trials systemically. Methods: CTRI database has 32 fields of mapping. Out of these, we have analysed 6 fields of this registry viz. public title, scientific title, study type, intervention and primary outcome. Conclusion: There should be not only encouragement but also compulsions among the research officers, academic teachers and private practitioners of Ayush systems for conduction and registration of Vaman/ Vamana clinical trials. Panchkarma specifically Vaman/ Vamana clinical trials must include procedural as well as therapeutic evaluation, clinic–comparative assessments and efficacy in diseases which are not mentioned in classical texts.

Keywords: Vaman/Vamana, CTRI, Intervention, Public title, Scientific title, Primary outcome.

1. INTRODUCTION

In September 2004, ICMJE (International Commission of Medical Journal Editors) implemented a dramatic and important policy for the condition of publication of clinical trials.¹,² The condition was that clinical trials must be registered in a public trial registry.³ Subsequently every region, country and regulatory authorities around the world prepared their publicly accessible registry and began posting of clinical trial information in their respective registry.

Clinical trial registry of India (CTRI) under the watchful eyes of ICMR is the primary registry of India. CTRI was established and launched on 20th July 2007.⁴ The primary objective of CTRI was declared to establish an authentic and complete public record of the clinical trials before the enrolment of first patient. Out of total clinical trials registered in CTRI, 3164 trials are from AYUSH system. DCGI declared that the registration of clinical trials will be mandatory with effect from 15th June 2009, PG theses and AYUSH faculty.⁵ It was advised to contact CCRAS for details of clinical trials conducted in Ayurved, Homeopathy, Siddha, Unani, Yoga and Naturopathy.⁶ It is expected that every clinical trial originating

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in India involving human participants for any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies and complementary therapies) must get registered in CTRI before enrolment of the first participant.7

In the Indian ancient system of health science Ayurveda guides about the prevention as well as treatment procures which are meant for the balance of three Doshas Vata, Pitta and Kapha. Specific Shodhan treatment Panchakarmas for the balance of specific Dosa has been advised viz Vaman/Vamana for Kapha, Virechan for Pitta and Basti for Vata Dosha.8 Diseases have been categorised according to the causative Dosa and simultaneously general guidelines for the Doshaj Vyadhis has been described as well as for specific disease the categorisation and specific treatments have been described.9 Vaman/Vamana is a treatment for the Kaphaj Vyadhis mentioned in the ancient texts of Ayurveda.10 Though it gives assuring results in many diseases it is a complicated procedure to conduct both for the Vaidyas and Atur.

Hence here an attempt has been made to analyse the data of Vaman/Vamana opted for the intervention and / or comparator agent in clinical trials which are registered in CTRI.

2. MATERIALS AND METHODS

2.1. Objectives

The objective of this study was to collect the data of Panchakarma- Vaman/Vamana clinical trials registered in CTRI and analyse it systematically. 73 clinical trials were registered in CTRI database on 01 July 2020 and we analysed this database on 1st July 2020 with last refreshed on 4th July 2020.

2.2 Materials

Out of total clinical trials registered in CTRI, 3164 trials were from AYUSH system. CTRI database has 32 fields of mapping. Out of these, we have analysed 6 fields of this registry: public title, scientific title, study type, intervention and primary outcome.47

2.3 Method (Registry search Strategy)

Out of very precise, precise, very sensitive, sensitive key word search strategy, we adopted just one term for key word search strategy for this study.11 73 clinical trials were registered in CTRI database and we downloaded this database on 1th July 2020 with last refreshed on 4th July 2020.

2.4 Inclusion criteria

Clinical trials enlisted in CTRI retrieved on 1st JULY 2020 which was last refreshed on 4th JULY 2020. IT includes key word from public title, scientific title, intervention & primary outcome. Total number of trials enlisted in CTRI is 73.

2.5 Exclusion criteria

Surgical interventions and other clinical trials from CTRI but not having Vaman/Vamana karma as intervention.

3. RESULTS AND DISCUSSIONS

We have analysed results and find discussions as follows. There are only 73 (2.5%) Vaman/Vamana trials, out of 3164 trials from AYUSH system. From 2017 there is steady increase in trial registration, with peak of trials registered in 2018 with 22 trials. No Vaman/Vamana trial was registered before 2012. (Figure 2).

93% of trials are interventional study type trials, while 7% trials are observational trials. It is but natural that Vaman/Vamana as procedure as well as effective therapeutic regimen interventional study type dominates the scenario. (Figure 3A)

Figure 3B suggest how the trials are registered. With effect from 1st April, 2018, CTRI began accepting studies only if they are prospectively registered. Since 1st April 2018 any researcher who plans to conduct a trial involving human participants, of any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies and complementary therapies) is expected to
register their trial in the CTRI before enrolment of the first participant. Hence 34 (45%) trials are registered retrospectively, 40 (55%) trials are registered prospectively.

Table 1 shows primary health condition or problem studied in Vaman/Vamana trials. 30% trials are concentrated on skin disease with Ekakushtha is leading of this. While Sthoulya/Medoroga/Prameha carries 19% of clinical trials. 13% trials are on Tamak Shwas/Kasa. 11% trials are on modern medicine lifestyle disease i.e. hypothyroidism (common disease). All these health condition collectively form kaphaj roga which is accordingly an ayurvedic principle. (For kaphaj roga, Vaman/Vamana is choice of treatment). Another 13% trials are on Vaman/Vamana as a procedure.

Table 2 shows interventions and comparator agent. For this study we have selected Vaman/Vamana as not only interventions but also comparator agent. 35% trials are as interventions with shaman chikitsa, where it is either intervention or comparator agent. 20% trials of Vaman/Vamana are purely intervention where it acts as a medicine.

36% trials are clinico-comparative trials consists of Vaman/Vamana along with other karma virechana (29%), basti (3%), raktamokshan (3%) and nasya (2%) included in these trials. These trials also include shaman chilkitsa as comparator agent.

This Figure also show trials which are directed towards the various aspects of purva karma of Vaman/Vamana (6%) and trials on various aspects of pradhan karma of Vaman/Vamana (4%). These trials evaluate different aspects of Vaman/Vamana as a procedure which are mentioned in classical basic texts i.e. samhita.

It is evident from Table 3 that Vaman/Vamana trials are institutional and academic base trials. No single trial is registered from individual investigator in an independent set-up (private clinic set-up). 70% trials are performed during post-graduation for M.D. thesis, 14% trials have been performed during Doctoral degree for Ph.D. dissertation while 15% trials are conducted by academic teachers in the graduate and post graduate institutes.

Figure 4 suggests, 40% of these trials are from national institutes and private universities equally. National institutes e.g. IPGT&RA, NIA, AIIA and B.H.U. and private deemed universities compete for the first position in the site of the study. Only 20% trials are conducted in Government Ayurved College and Hospital set-ups. National institutes are funded by central government and they are the autonomous bodies while Government colleges and hospitals are funded by the respective state governments and they are governed by the state directorate of AYUSH.

4. CONCLUSION

There is very low awareness about the registration of Vaman/Vamana clinical trials among the academicians and practitioners of Ayush health system. There should be not only encouragement but also compulsions among the research officers, academic teachers and private practitioners of AYUSH systems for conduction and registration of Vaman/Vamana clinical trials. Panchkarma specifically Vaman/Vamana clinical trials must include procedural as well as therapeutic evaluation, clinical – comparative assessments and efficacy in diseases which are not mentioned in classical texts.

REFERENCES


**TABLES / FIGURES**

![Figure 1. Vaman/Vamana: CTRI search portal](image1)

![Figure 2. Total Vaman/Vamana trials registered in CTRI on Yearly Basis](image2)
Vyas SD, Khairnar NR, Vyas KS. A Systemic Review of Vaman Clinical Trials registered in CTRI.

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**SN** | **Disease**                                               | **No. of Vaman Trials** |
-------|-----------------------------------------------------------|------------------------|
1      | **Ekkushtha, Shwitra, Tarunyapitika**                     | 22                     |
2      | **Prameha, Medorog, Sthoulya, Dyslipidaemia**             | 14                     |
3      | **Tamak shwas, Kaas**                                     | 9                      |
4      | **Vaman Karma**                                           | 9                      |
5      | **Hypothyroidism, Thyroid dysfunction**                   | 8                      |
6      | **Amlapitta**                                             | 4                      |

**TRIALS(73)**

- NATIONAL INST. (28)
- GAC & GMC (17)
- PRIVATE INST. (28)

Figure 3A: Study Type

Figure 3B: Trials Registration

Figure: 4 Distributions of trials according to site of the study.
Table: 1 Trials according to primary health condition(s) or problem(s) studied

<table>
<thead>
<tr>
<th>SN</th>
<th>Disease</th>
<th>No. of Vaman Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Kashta Artav, PCOS</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Pandu</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>Allergic rhinitis</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>Divaswaap</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>Rasayan</td>
<td>1</td>
</tr>
</tbody>
</table>

Table: 2 Trials according to intervention/s and the comparator agent

<table>
<thead>
<tr>
<th>SN</th>
<th>Interventions /Comparator Agent</th>
<th>No. of Vaman Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vaman and Shamana</td>
<td>24</td>
</tr>
<tr>
<td>2</td>
<td>Vaman and/or Virechana and/or Shamana</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>Vaman as Medicine</td>
<td>14</td>
</tr>
<tr>
<td>4</td>
<td>Vaman and/or Basti and /or Shaman</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>Vaman and /or Raktamokshan</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Vaman and/or Nasya and /or Shaman</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>Purva Karma of Vaman(procedure)</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>Pradhan karma (procedure)</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3: Distribution of trials according to Primary Investigator.

<table>
<thead>
<tr>
<th>SN</th>
<th>Designation of Primary Investigator</th>
<th>No. of Vaman Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PG Scholar</td>
<td>51</td>
</tr>
<tr>
<td>2</td>
<td>Assistant/Associate/Professor</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>Ph.D. Scholar</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Research officer</td>
<td>1</td>
</tr>
</tbody>
</table>