

Homoeopathic Medicines As Adjuvant Therapy In The Management Of Bleeding Episodes And Pain In Hemophilics

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Key words:

Haemophilia, Pain relief, Haemarthrosis, Developing country, Thrombostat, Genetic Constitutional Similimum, Adjuvant therapy.

Background:

Hemophilia is an X-linked genetic disorder where the mechanism of coagulation is defective. 90% of severe hemophiliacs live in developing countries, where appropriate health care resources are severely limited. Conventionally, these patients are treated with required factor infusion and later on by physiotherapy. Now factor infusion being very costly, a majority of patients cannot afford it even when it is required. In such a scenario, prophylactic factor infusion in country like India with huge number of needy patients, is indeed a very difficult task as compared to the developed nation where factor infusion are given on a regular basis from birth as a prophylactic measure. Moreover pain relief in these patients is also suboptimal as except paracetamol other analgesics which can be given to these patients safely are not easily available in India.

Hence the present study was conducted on efficacy of Homoeopathic medicines in the management of bleeding episodes of hemophiliacs in a double blind placebo controlled trial.

Materials and Methods:

53 consecutive patients with hemophilia (A&B) received standard management as is given in this centre along with placebo homoeopathic medicines for 1 year. Thereafter they received the same management with active homoeopathic drugs in subsequent year. Transfusion requirement, bleeding scores and pain score were evaluated by blind evaluators.

Homoeopathic medicines were selected by experienced homoeopathic physicians by using a combination of constitutional therapy & acutely acting polychrest medicines depending on clinical condition of the patients. Standard statistical evaluations were used to evaluate the difference in scores with and without active homeopathic medicines under following criteria:

- 1) Frequency of (open & closed) bleeding.
- 2) Duration of healing.
- 3) Factor requirement.
- 4) Pain Score ratings

Result:

Addition of properly selected homoeopathic medicines by homoeopathic physicians not only improved the subjective well being of hemophilic patients during the therapy, there were also significant and

noticeable improvement in the frequency of (open & closed) bleeding episodes, duration & extent of bleeding, amount of blood product consumed and in pain scores ($p < 0.0001$).

Conclusion:

Well selected homoeopathic medicines by homoeopathic physicians proved to be efficient in managing the bleeding episodes of hemophiliacs there by improving their quality of life at home, workplace & school. Similarly it was found that the subsequent reduction in factor infusion not only lessened the economic burden on the family but also reduced anxiety on the part of the patients and the society as well.

Introduction:

Hemophilia is an X- linked genetic disorder where the mechanism of coagulation is defective, especially related to factor VIII or IX. A hemophilic patient does not bleed more intensely than a normal person but for a longer period of time, there by wasting a lot of precious blood. The amount of blood loss during each episode depends on site affected or injured, duration of bleeding and frequency of bleeding episode. It become more disastrous when the bleeding is concealed i.e. bleeding joint spaces (haemarthrosis) & bleeding in body cavities (intracranial (1) & intracoelemic) . Conventionally these patients are treated by required factor infusion, which being very costly, a majority of patient cannot afford it even when needed. The factor concentrate are very costly mainly because they are imported and have deficient supply in almost all chapters of India (2) as in West Bengal(3).

It was estimated in a survey that, for the easy availability of factor to PWH in India, the country has to be self sufficient with 100 million units of factor VIII concentrates & 200 million units of factor IX concentrates which is a formidable task at the moment.(4)

So in present scenario, factor infusion on a prophylactic measure to the PWH is certainly very difficult & even when they are sparingly infused they have chances of developing factor inhibitor(5), which is one of the major problem faced by developed nations. Likewise the risks of transmission modalities like Hepatitis B & C and HIV increases fore fold with the frequent use of blood products adding further more misery to the patients.

To sum up, in order to facilitate the needs of hemophiliacs, it is important to exploit the scope of alternative medicine like Homoeopathic medicines. They are not only cost effective but also serve as effective supportive therapy for the betterment of hemophiliacs.

Materials And Methods:

53 Consecutive patients with hemophilia A & B received standard management as is given in this center along with placebo homoeopathic medicines for 1 year, thereafter, they received the same management with active homoeopathic medicines in subsequent years.

Patients were diagnosed as Hemophilia and the severity was classified with factor assay from National Institute of Immunohaematology at KEM Hospital, Mumbai. Relevant consent from the patients and their parents for the trial was taken & the study was sanctioned by Institutional review board.

The patients were interviewed according to the homoeopathic principle of case taking and the data was entered in a specific case record format (6). After formative analysis and evaluation, the indicated medicine was prescribed by experienced homoeopathic physician

(6, 7)The action of the medicines has been analytically observed as per Dr. Kent's observation All the patients kept a diary noting the number of bleed, amount of factor concentrate/blood product consumed, treatment taken for pain relief, days of absence from school/workplace, daily activities, behavioral changes during pain etc. They were regularly given physiotherapy by AN.

These Patients were periodically evaluated at an interval of 3 months under following criteria:

1. Wong Baker pain rating scale (8).
2. Frequency of bleeding and control measures.
3. Joint mobility and functioning were blindly evaluated by AN and SK.

Treatment Plan:

In case of acute bleeding / swelling -RICE therapy is given i.e. Rest, Ice, Compression and Elevation along with Homoeopathic thrombostatic drug i.e. Hamamelis Virginica Q which is used along with ice to give cold fomentation at the affected site. When a larger area is injured we add 50 drops of Hamamelis Q in 200 ml of icy cold water and apply locally. We have observed that Hamamelis Virginica, due to its astringent effect causes tightening up of protein in the skin and across the surface of abrasion. This creates protective covering that increases resistance to inflammation and promotes healing of broken skin. Unlike Hamamelis Virginica, Arnica Montana has property of reabsorption of blood from the injured tissues which breaks the clot and resumes the bleeding (9, 10, 11) that is why Arnica seems to be contraindicated in active bleeding phase.

Acutely acting drugs for pain and swelling along with RICE therapy are orally administered considering acute totality criteria like nature of injury, sensation, modalities(12), sides affected and only when the indicated medicine have no antagonist relation with constitutional medicine as per Gipson Miller remedy relationship chart(13).

Genetic constitutional similimum (14) is administered during non- bleeding phase. The selection depends on his basic disposition, constitution, temperament any dominant behavior of the patient, upbringing of the child and any other important incidence in life, its impact on the patient and feeling developed in response to it.

Results:

There was substantial reduction of frequency of bleeds during active homeopathic therapy ie from 7.25 +/- 7.15 to 0.75 +/- 1.08(m+/-1sd) $p < 0.0001$, similarly factor usage ($P < 0.0001$), days of absence from school or work($P < 0.0001$) significantly improved on supportive therapy(Table 1).

Pain score on this management in 53 patients also showed significant changes ($P < 0.0001$) and was associated with marked reduction in usage of analgesics.(Table2).

Though it was not quantified but qualitatively range of movement improved in all the affected joints.

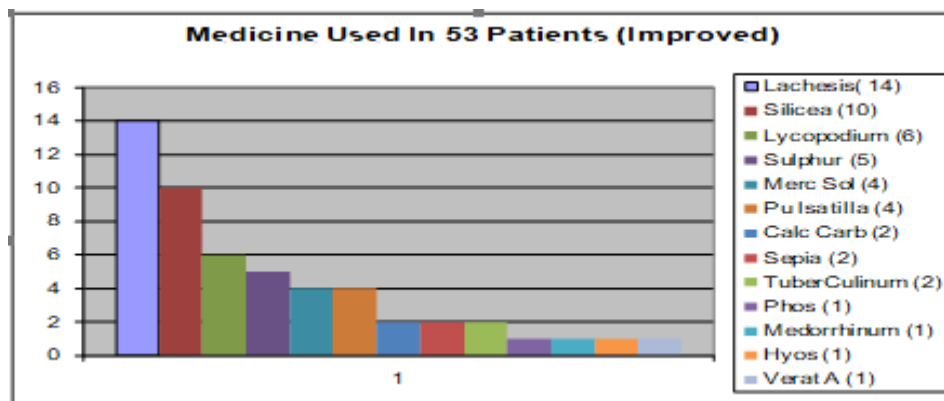
Discussion:

Modern management of severe and moderate hemophilia mainly depends on adequate treatment with missing factor concentrates, pain relief using relevant medicines (In India mostly paracetmol) and regular physiotherapy, all other modalities of treatment for various complications of this disease, centers around a comprehensive care facility and being a genetic disorder genetic counseling and in many countries carrier detection and prenatal diagnosis forms important components of the management strategy for

hemophilia patients. However in developing country one of the major problems is non- availability of adequate amount of factor concentrates mainly due to financial reasons, till the time comes when the country is able to provide adequate factor concentrates to every needy PWH, we see an opportunity to study the efficiency of Homoeopathic medicines in managing the bleeding episodes in hemophilia.

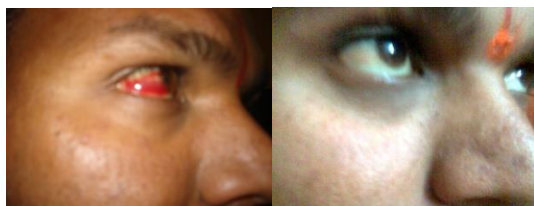
In order to substantiate the above point, let us understand how Homoeopathy can help in managing hemophiliacs. As hemophilia is a genetic disease, here the defective gene determines the disease. Likewise gene is responsible for determining so many other factors in humans e.g. colour of eyes, complexion of skin, texture and colour of hairs, tendencies (diathesis) towards certain diseases, behaviour of person and his reaction to surrounding environment etc.

Therefore, Homoeopathic genetic similimum focuses mainly on these factors which are the determinants of gene, in order to form the basis of prescription. Most frequently prescribed medicines on this basis during the trial were Lachesis, Silicea, Lycopodium, Sulphur, Merc sol, Pulsatilla, Calc carb, Sepia, Tuberculinum, Phosphorus (15), Medorrinum, Hyoscymus, Veratrum Album, Opium, Platina etc..



Cases:

- 1) **H-16** is a 27 year old patient suffering with severe hemophilia had 60% disability with key lesion at in his left knee joint. In 2003, he suffered with left sided hemiplegia and was in coma for a month due to head injury. Scan reports showed intracranial bleeding in right temporal region in circle of Willis. Lachesis was prescribed to him after studying his behavior which was fearless, frivolous and had marked perseverance. After the medicine he showed remarkable improvement in his disability which got substantially reduced to 40% from 60% disability. The same drug helped him to relief his complaints, when he suffered from sub- conjunctival hemorrhage in past with no factor usage. In Last 2 years, since on homoeopathic medicines he required factor only once, Unlike 2 years ago when he consumed factor worth Rs 5 lakh.



Before

After



Before

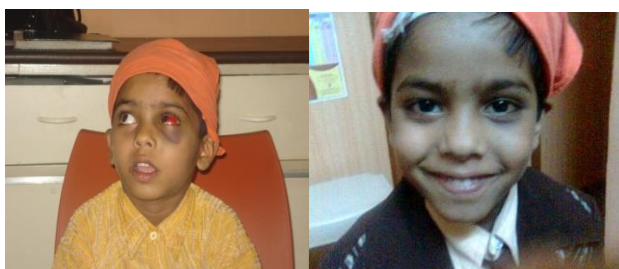
After

2) **H-33** –Is a 9 year old boy, a severe haemophilic who suffered with sub- conjunctival hemorrhage following a scalp injury and was completely relieved by medicine within 7 days without any factor infusion. His brief medical history as follows:

On **9th July 2009**- had a head injury with stone, there was bleeding with scabs. No factor was needed only Hammelis Q was applied locally.

On **25th July 2009**- Again suffered a left temporal head injury which resulted in sub- conjunctival hemorrhage of right eye. Phosphorus was given after observing his behavior which was foppish, had interest in clothes.

On **2nd Aug 2009**- After 7 days his eye complaints were completely relieved.



3) **H-24** – Is a 3 year old boy suffering with severe Haemophilia had an injury on lower lip which resulted in continuous oozing of blood.

On **23rd & 24th Aug 2009**- Factor of 2500 U. was given. But oozing of blood continued. Then Elaps cor 200 was given on basis of following rubrics:

- a) Generalities, hemorrhage, blood clot dark.
- b) Biting himself.

On very next day – clot excised without the use of factor, only hammelis Q was used as thrombostat.



Similarly, acute drugs were prescribed on the criteria as mentioned earlier –

But few drugs were found to have worked wonderfully during the trials, in managing certain acute conditions and are worth mentioning like:

1) In cases where patients suffered muscular swelling due to internal bleeding, **Calcarea carb 1M** showed good result in resolving the swelling and reduced duration of healing time. (Case: **H-60** is a 12 year old boy who suffered from huge muscular haematoma over anterior chest wall. It got resolved within **3 days** after giving **calc carb 1M**.)

Pathophysiology: Insufficiency of calcium in the wall of small blood vessels causes them to break down under excessive changes of temperature, to an inability of the blood to clot on exposure to

air as in **haemophilics** (16). When calcium supplemented, it lessens the coagulation time and favors the formation of clot.

- In few patients **Calcarea carb** showed very good results, which are fair, fat, and flabby. In haemophilics **Calcarea (Ca)** is usually supplied for nutritional supply and nutritional status (Subcutaneous fat)
 - Calcium can also be given in combination as **Calcarea phosphoricum** in cases where there was difficult reabsorption and remodeling of bones, open fontanelles, rickets and in cachexia.
 - **Calcarea fluorica** is indicated in swelling and pain of joints due to excess physical exertion causing straightening and stressing of muscle fibers and ligaments e.g. working in field or in case of chronic synovitis.
2. In cases where there was swelling of knees with effusion and cold amelioration as the particular modality –**Apis melfica 30** was frequently indicated. It acts in cases where there is rapid oedematous inflammation with burning and stinging pain. In **Apis** effusion is more marked than hyperaemia (17).
 3. Pain and swelling of knee joints, better by rest and pressure and aggravated by motion was frequently responding to **Bryonia 30**. It acts on serous and synovial membrane of joints causing irritation and inflammation +3 of tissues with accumulation of serous and synovial exudates in the joint space resulting in swelling of joints & articular spaces and severely restricted movement (18).
 4. Knee pain better by icy cold water indicated at times **Ledum Pal 30**. It retards the capillary circulation and there is coldness of extremities. Articulation of small joints are enlarged and there are deposits and nodosities (19).
 5. **Strontium carb 30** was efficient in cases of muscle and tendon shortening or contracture due to frequent bleeding in same joint, leading to difficulty in walking and abnormal gait. It is also indicated in cases where there was chronic sequelae of hemorrhage (20) and specifically psoas bleed.
 6. **Crocus Sativa-30** - In cases where blood was dark and stringy, clots with long strings.
In our Phase 2 trial considering **Kleijnen criteria** the score is little robust i.e. 75 out of 100 which is quite better than placebo effect (21).

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References:

1. K.Ghosh, A.P.Nair, F.Jijina, M.Madkaikar, S. Shetty, D.Mohanty. Intracranial haemorrhage in severe haemophilia: prevalence and outcome in developing country, *haemophilia* (2005), 11,459-462.
2. Ghosh K, Shetty S, Sahu D. Haemophilia care in India: Innovations and integrations by various chapters of Haemophilia federation of India (HFI). *Haemophilia* 2009; accepted for publication
3. Bandopadhyay Parijat, *Anandabazar patrika*, supplement Kolkata page 1, column 6,7,8.

4. Ghosh K. Management of Haemophilia and its complication in developing countries. Clin.lab.haem.2004, 26, 243-251.
5. Ghosh K, Jijina F, Shetty S, Madkaikar M, Mohaty D. First time development of F VIII inhibitor in haemophilia patients during the post operative period: Haemophilia 2002, 8,776-780.
6. Hahnemann Samuel Organon of Medicine 6th edition, Aphorisms 83-104, Organon of Medicine, 6th Edition. B. Publication. N. Delhi.
7. Kent, James Tyler. Lectures in Homoeopathic Philosophy. Prognosis after administration of Homoeopathic medicine. B.Jain Publications, New Delhi.
8. Wong DL, Hockenberry-Eaton M, Wilson D, Winkelstein ML, Schwartz P: Wong's Essentials of Pediatric Nursing, 6/e, St. Louis, 2001, P 1301
9. Heimans B., Geïllustreerde Flora van Nederland, Amsterdam .
10. The book –Prisma by Dr. Vermeulen Franz
11. [Action of Metalloproteinases Mutalysin I and II on Several Components of the Hemostatic and Fibrinolytic Systems by:-
Maria I. Estêvão-Costa, Carlos R. Diniz, Arinos Magalhães, Francis S. Markland and Eladio F. Sanchez
Centro de Pesquisa e Desenvolvimento, Fundação Ezequiel Dias, Belo Horizonte, Brazil, 30510-010
Dept. de Bioquímica e Imunologia, Universidade Federal de Minas Gerais, Belo Horizonte, MG.
Brazil
Department of Biochemistry and Molecular Biology, University of Southern California, Keck School of Medicine]
12. A Synoptic Key to the materia medica by C.M. Boger, MD, B. Jain Publishers (P) Ltd
13. 17, 20, Pocket Manual of Homoeopathic Materia Medica with Clinical and Pathogenetic Symptom by William Boericke: Gibson Miller relationship of remedies, B. Jain Publishers Pvt. Ltd. New Delhi., Pg 63, 613.
14. The Genetic Constitutional Similimum by Vijaykar Prafull-: Theory of suppression, 4th edition, page 57-132, Published by Mrs Preeti Vijaykar, Dadar, Mumbai-400028, India.
15. Haemorrhagic tendency from any wound-even haemophilia by Roger Morrison, MD: Desktop Guide by Homoeopathic Medical Publishers, Mumbai, Page 293.
16. ,18, A Manual of Homoeo- Therapeutics, An Introduction to the Study and Practice of Homoeopathy, by Edwin A. Neatby, M.D ,Thomas G Stonham, M.D, Pg- 277, 260, 255.
19. A Manual of materia medica Therapeutics and pharmacology with clinical index by Alexander L. Blackwood, Pg 421.
21. Kleijnen J, Knipschild P, Ter Riet G. Clinical trials in homeopathy. Brit. Med. J. 1992; 302:316-23.

Table 1. Changes in frequency of bleeds , factor concentrate requirements and absenteeism due to consequences of haemophilia before(placebo) and after homeopathic treatment*.

Patients (53)	Frequency of blood/year	Factor usage rate/ i.u./year	Absenteeism in days/year
On Placebo (Range)	7.25 ± 7.14 (2-30)	3617 ± 3361 (1000 – 12,500)	50.4 ± 27.6 (8-111 days)
On homeopathy treatment (Range)	0.75 U ± 1.075 (0-5)	632 ± 1077 (0-5000)	4.75 ± 8.20 (0-40)
Paired t test	t = 5.3096 df =27 P>0.001	t = 5.7667 df = 27 P<0.001	t = 8.3723 P<0.001

*Management with RICE, factor concentrate and physiotherapy continued in 28 patients of PWH both while on Placebo and on active homeopathic medication .