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## Safety of homeopathic polypharmaceutical formulations in homeopathic practise

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### ABSTRACT

Homeopathic medicines were never subjected for long term safety follow up since its inception. They were effective in the treatment of range of diseases based on the principal of symptom similarity. Nevertheless treatment with homeopathic medicines in practise and principles can give rise to few safety issues like Schein's symptoms (symptoms of excess medicine), conjoint malady and incurable disease other than its usual pathogenetic phenomena. The objective of present investigation was carried to demonstrate the safety of use of homeopathic formulation more than single medicine at a time (polypharmacy) in suitable doses and repetitions. This was retrospective design aimed to study rate of occurrence of different parameters like Schein's symptoms, conjoint malady and incurable diseases after polypharmaceutical prescription of homeopathic remedies. Data was expressed as odds ratio and relative risk for all the three variables namely, schein's symptoms, conjoint malady and sub curable disease. Total of 635 cases studied with nearby equal proportion of both sexes [(355 (55.9%) males and 280 (44.1%) females)] from all age groups including paediatric age group 20 (3.14%). Treated conditions were chronic headaches, alopecia areata, urolithiasis, hypothyroidism and benign prostatic hyperplasia [BPH] 33 (5.2%), diabetes mellitus [DM] 27 (4.25%). Background therapy of conventional medicine was not found to be discontinued for the hypothyroidism and diabetes mellitus. The relative risk and odds ratio for Schein symptoms, conjoint malady and incurable disease were 2.554, 3.647, 2.242 and 15.310, 57.652, 6.383. In conclusion, use of homeopathic polypharmaceutical formulations was found to be safe and associated with minimal risk ( $P < 0.0001$ ).

### INTRODUCTION

Ever since dawn of homeopathy, safety of homeopathic dilutions was never so interestingly studied and discussed topic [1, 2]. Subtly the homeopathic formulations are considered safe and efficacious [3]. Many clinical trials are conducted all over globe for many popular diseases which yielded ambiguous but some fruitful results [3, 4]. Some studies have shown that clinical trials were conducted resulted in high quality outcome on the other hand metaanalysis conducted depicted that it was sheer placebo effect. Besides efficacy, safety of the individual is also of utmost importance in good clinical practices irrespective of treatment modality [5, 6]. Conventional medicine has different steps to prove their medicines which are to be safe first and then should be efficacious which now globally accepted guideline is. Complementary medicine lags behind exactly in this case [7, 8]. In this case say particularly of homeopathy, 'toxicity' of dilutions remains undertrained, because not a single particle of mother substance is evident in potencies after 23X [9, 10].

Preclinical and clinical studies already have shown positive results regarding safety of homeopathy [11]. Polypharmacy is one more challenge to law of single remedy and single dose [12-15]. Moreover other than traditional and so called classical group of homeopaths the use of homeopathic patents and prescription of more than single homeopathic medicine is widely accepted practise or fashion across globe and India. Hahahnemann in his famous book 'Organon of medicine' had quoted several demerits of polypharmacy like conjoint malady, incurable disease and Schein's symptoms [16, 17]. Today where the disease itself is considered as multifactorial obnoxious process and sufferings of human being; it's hardly possible to match single remedy with entire symptom totality as

the disease has much or partially suppressed [18-24]. Not only suppressed but also has alternating as well as one-sided symptoms [25-35]. Sometimes it's really very tough and patience testing phase for both physician and patients [36]. To overcome this challenge and to restore the sick to health it is sometime utter necessary to choose polypharmacy approach as treatment option without surpassing the importance of classical homeopathy.

## MATERIALS AND METHODS

The present investigation was carried to demonstrate the safety of use of homeopathic formulation more than single medicine at a time (polypharmacy) in suitable doses and repetitions. This was retrospective design aimed to study rate of occurrence of different parameters like Schein's symptoms, conjoint malady and incurable diseases after polypharmaceutical prescription of homeopathic remedies. One time data was archived for duration (year, Jan 2003-July 2014) from Sanjeevan Homeopathic clinic and research centre, Pune (India). Data was collected, identified and segregated for variables like symptoms of excessive medicine (Schein's symptoms), drug disease (conjoint malady) and incurable disease (sub curable disease). Definitions of variable terms were taken and used from Organon of medicine, 6<sup>th</sup> edition authored by Dr. Samuel S. Hahanemann. Cases were merely divided in two groups namely exposed to polypharmacy and control (not exposed to polypharmacy). Outcomes were assessed as positive and negative for above mentioned three parameters representing so called adverse outcomes from implementation of more than single homeopathic medicine (polypharmacy).

**Statistical analysis:** Variables derived from identified data were analysed using Altman, 1991 [37]. Data was expressed as odds ratio and relative risk for all the three variables namely, Schein's symptoms, conjoint malady and sub curable disease. The relative risk (RR), its standard error and 95% confidence interval are calculated according to Altman, 1991. The relative risk or risk ratio is given by with the standard error of the log relative risk being and 95% confidence interval. Similarly The odds ratio (OR), its standard error and 95% confidence interval are calculated according to Altman, 1991 [37].

## RESULTS

Total of 635 cases studied with nearly equal proportion of both sexes [(355 (55.9%) males and 280 (44.1%) females] from all age groups including paediatric age group 20 (3.14%). Out of 635 treated cases 240 (37.8%) cases were exposed to polypharmacy and 395 (62.2%) were not exposed to polypharmacy by any chance. Treated conditions were chronic headaches 459 (72.8%), alopecia areata 120 (20.15%), urolithiasis 79 (12.44%), hypothyroidism 40 (6.3%) and benign prostatic hyperplasia [BPH] 33 (5.2%), diabetes mellitus [DM] 27 (4.25%). Background therapy of conventional medicine was not found to be discontinued for the hypothyroidism and diabetes mellitus. The relative risk and odds ratio for Schein's symptom was 2.554 and 15.310 respectively at 95% confidence interval (Table 1 and 2). The relative risk and odds ratio for Schein's symptom was 3.647 and 57.652 respectively at 95% confidence interval (Table 3 and 4). The relative risk and odds ratio for Schein's symptom was 2.242 and 6.383 resp. at 95% confidence interval (Table 5 and 6).

**Table 1. Odds ratio and *p* value for 'Schein's Symptoms'**

Odds ratio	95% CI	z Statistic	<i>P</i> value
15.3101	7.7226 to 30.3523	7.814	<i>P</i> < 0.0001

**Table 2. Relative risk and *p* value for 'Schein's symptoms'**

Relative risk	95% CI	z Statistic	<i>P</i> value
2.5554	2.2113 to 2.9532	12.712	<i>P</i> < 0.0001

**Table 3. Odds ratio and *p* value for 'conjoint malady'**

Odds ratio	95% CI	z Statistic	<i>P</i> value
57.6522	23.0096 to 144.4514	8.652	<i>P</i> < 0.0001

**Table 4. Relative risk and *p* value for 'conjoint malady'**

Relative risk	95% CI	z Statistic	<i>P</i> value
3.6473	3.1411 to 4.2350	16.975	<i>P</i> < 0.0001

**Table 5. Odds ratio and *p* value for 'incurable disease'**

Odds ratio	95% CI	z Statistic	<i>P</i> value
6.3833	3.2749 to 12.4421	5.444	<i>P</i> < 0.0001

**Table 6. Relative risk and *p* value for 'incurable disease'**

Relative risk	95% CI	z Statistic	<i>P</i> value
2.2423	1.8608 to 2.7020	8.486	<i>P</i> < 0.0001

## DISCUSSION

Homeopathy is a popular complementary medicine practised worldwide. Clinical practise in homeopathy categorizes response to polypharmacy chiefly under the label of conjoint malady, Schein's symptoms and incurable disease [11, 38-47]. The retrospective data analysis of the study data yielded possible risk associated with development of aforementioned outcomes. Health has been defined as physical, mental and spiritual soundness of human life and absence of any pain and disability. The healing and disabling properties of drugs and chemicals have been studied during the evolution of modern medicine [48-57].

Six thirty five [635] cases were studied including paediatric age group of both sexes. Therapeutic indications studied were alopecia areata, chronic headaches, hypothyroidism, BPH, urolithiasis and DM. The relative risk of developing Schein's symptoms was very minimal (2.554) with odds of (15.3101) (Table 1 and 2). The relative risk of developing conjoint malady was also very small (3.6473) with odds of (57.6522) (Table 3 and 4). The relative risk of developing incurable disease was as petite as rest two outcomes i.e. (2.2423) with odds of (6.3833) (Table 5 and 6). All above values were reported at 95% confidence interval. Overall the outcomes were statistically significant (*P* < 0.0001).

The present investigation showed precise result in the context of homeopathically opted outcomes. Use of polypharmaceutical homeopathic formulations proved to be safe and tolerable. Extensive use of polypharmaceutical formulations can be safely employed in clinical practise. Need for more perfect and longitudinal study design cannot be overridden in spite of above encouraging results. This study only represents the sample from monocentric design and warrants the extended use of polypharmaceutical formulations in homeopathy for various clinical conditions exclusively in multicenter trials.

## CONCLUSION

Use of homeopathic polypharmaceutical formulations was found to be safe and associated with minimal risk (*P* < 0.0001) of developing all the three parameters (Schein's symptoms, conjoint malady and incurable disease) which put forward the necessity of high quality design for further multicentre studies and generation of more unbiased outcome.

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