Research Article

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BIOCHEMICAL EFFECT OF PARSEEK YAVANI AS PRE-ANESTHETIC AGENT IN RELATION TO KETAMINE ANESTHESIA

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ABSTRACT

There are many paths which lead to the acquisition of clinical knowledge that might profitably be explored, but there is only one high road to increase the therapeutic knowledge and that is the controlled clinical trial. The importance of clinical trial cannot be overlooked. This is the only way to confirm the experimental observations, claims made by previous workers and also to find out additional action and side effects, which are sometimes observed only in human beings. The drug Parseek Yavani (*Hyocyamus niger*) has been found to have analgesic, antisialagouge and sedative effects. So, the plan to study the trial drug as pre-anesthetic agent with special reference to its biochemical effect in relation to Ketamine anesthesia was taken up on patients according to American Society of Anesthesiologist Grade 1. Aims of present research work was to know the bio-chemical variation in the body after administration of research drug, to study the side effects of drug if any, to put forward an ideal and safe drug for pre-medication in Sangyaharana (Anesthesia) and to establish the efficacy of Ayurvedic drug in the field of pre-medication in Sangyaharana. The results of the study shown significant rise of Alkaline Phosphatase value ($P < .001$) before and after premedication in trial group as compared to standard group while other biochemical changes were insignificant.

Keywords: Parseek Yavani, pre-anesthetic agent (premedication), biochemical effect, ASA (American Society of Anesthesiologist), alkaline phosphates.

INTRODUCTION

The entire science of Ayurveda has been framed on Trisutra[1] Hetu, Ling and Aushadh. Among these Aushadh (drugs) is like an instrumental aid to the physician and is placed second[2] under the Chikitsa Chatushpada. Acharya Charaka has rightly said that a drug that is not understood perfectly is comparable to poison, while the perfectly understood drug is comparable to ambrosia. Hence, the success of treatment depends upon the genuineness and the quality of the drug. The term pre-medication[3] was 1st used in 1920 by Mc Mehan. Its purpose is the administration of drugs to facilitate the induction, maintenance and uneventful recovery from anesthesia. The value of proper choice of premedication was emphasized by Dripps, Ekenhoff and Vandam (1957), who stated that it could pave the way for smooth induction of anesthesia and post operative course. At present Morphine, Pethidine, Pentazocine, Promethazine, Diazepam, Atropine, Hyoscine, Glycopyrrolate etc are widely used in India as pre-anesthetic agents. They are used for having analgesic, sedative, tranquillizing, anti-secretory and cardiovagolytic action. Most of these drugs are not free from side-effects and hence have several drawbacks. Inspite of a lot of work done in the field of anesthesia, no single drug can fulfill the criteria of an ideal pre-medication drug. Keeping in view the above facts, a search work was made in Ayurvedic literature where a number of vednasthapan dravyas have been mentioned. Pain-relieving drugs are the main constituents in the armory of anesthetist since the time of Lorenzo Bruno of Turin, who advocated the use of opium as pre-anesthetic medication in 1850. Research worker Awasthi P. 2003 has also proved the usefulness of this drug in the field of anesthesia as pre-anesthetic medication drug. This drug has certain anti-anxiety, analgesic[4], anti-sialagouge and sedative[5] actions by which it produces dryness of mouth, thirst, sedation and quietening effect on the patients. Further to reveal that whether this drug is devoid of toxic effects, the present work entitled biochemical effect of parseek yavani as pre-anesthetic agent in relation to Ketamine anesthesia has been planned and chosen as a topic for research work.

MATERIAL AND METHODS

Selection of patients: Year of study 2002 - 2005

The patients in the present clinical study were normally taken and enrolled on the basis of inclusion criteria irrespective of sex within the age group 10-45 years. 20 patients were taken for this study and were randomly divided into two groups consisting of 10 each. According to A.S.A. scale all these patients were kept in grade one. All patients were admitted in the P.G. department of Shalya Tantra and Prastuti Tantra in affiliated hospital of Rajiv Gandhi P.G. Ayurved College, Paprola, Kangra, Himachal Pradesh, India for short elective surgical procedures.

Criteria for inclusion of patients

- Patient aged between 10-45 years.
- Patients undergoing short surgical procedures (anorectal, gynaecological, orthopedic).
- Routine hematological and bio-chemical investigations should be within normal limit.
- Chest X-ray, E.C.G. within normal limit.
- Urine routine and stool examination within normal limit.
- Patient of A.S.A[6]. Grade-I.

Criteria for exclusion of patients

- Patients not willing for trial.
- Patients below 10 years and above 45 years.
- Patients above A.S.A. grade-I

Grouping of the patients

- All the patients selected for study purpose were divided into two groups viz. standard and trial group consisting of 10 patients each.
- Patients were examined thoroughly before pre-medication followed by routine laboratory investigations to exclude any organic or metabolic disorders, which if present were excluded from the study.
- Patients of standard group were pre-medicated with injection Atropine Sulphate 0.6 mg intramuscular 60 minutes before the procedure. Before and 60 minutes after per-medication blood samples were taken to study the bio-chemical variation.
- The trial drug was given orally in the form of capsule (500 mg) to trial patients 90 minutes before procedure. Before and 90 minutes after pre-medication blood samples were taken to study the bio-chemical variation.
- All patients were given injection Ketamine intravenously in bolus as per-calculated dose from weight of the patient (2 mg/kg).

Objective criteria (bio-chemical changes)

Before and after (60 minutes/90 minutes) pre-medication by drug (standard/trial), blood samples were drawn to study the biochemical variations i.e. Serum Glutamate Oxaloacetate Transaminase, Serum Glutamate Pyurvate Transaminase, Alkaline Phosphatase, Total Serum Bilirubin, Blood Urea and Serum Creatinine. The blood sample was drawn before pre-medication and sent for bio-chemical evaluation. After that patient was pre-medicated 60/90 minutes before surgery or just prior to surgery, second blood sample was drawn and again sent for the bio-chemical evaluation. Both the values of first and second samples of bio-chemistry were compared whether the values were increased or decreased after pre-medication with standard and trial group respectively.

OBSERVATIONS AND RESULTS

In present clinical study, 20 patients were enrolled on the basis of inclusion criteria and were divided into two groups of 10 patients each. The groups were designed as follows:-

Division of Groups

Group	Pre-medication	Dose	Route
Standard group (S.G.)	Inj. Atropine sulphate	0.6 mg	I/M
Trial group (T.G.)	Cap. Parseek Yavani	500 mg	Oral

Evaluation of objective variables: Biochemical changes

Table 1: Mean blood sugar (mg %) changes before and after pre-medication and statistical comparison in both groups

Group	Mean value		% Age	SD ±	SE ±	t	p
	B.P.M.	A.P.M.	Increased /Decreased				
I (S.G.)	82.6	94.4	14.28 %	24.98	7.9	2.75	< 0.05
II(T.G.)	83.3	93.9	12.73 %	2.99	0.95	9.4	< 0.001

(I) Standard group, (II) Trial group; B.P.M. (before pre-medication, A.P.M. (after pre-medication)

Statistical comparison of mean blood sugar level before and after pre-medication in between the two groups

Group	SE ±	t	P	R
I and II	7.95	1.61	> 0.05	NS

(I) Standard group, (II) Trial Group

Table 2: Mean Serum Glutamate Oxaloacetate Transaminase Value (IU/L) change before and after pre-medication and statistical comparison in both groups

Group	Mean value		% Age	SD ±	SE ±	t	p
	B.P.M.	A.P.M.	Increased/Decreased				
I (S.G.)	28.8	38.2	32.64 %	492.03	155.7	.06	> 0.05
II (T.G.)	32.8	36.1	10.06 %	5.8	1.8	0.99	> 0.05

(I) Standard group, (II) Trial Group; B.P.M. (before pre medication), A.P.M. (after pre medication)

Statistical comparison of mean Serum Glutamate Oxaloacetate Transaminase value changes before and after pre-medication in between two groups

Group	SE ±	t	P	R
I and II	49.54	0.15	> 0.05	NS

(I) Standard group, (II) Trial Group

Table 3: Mean Serum Glutamate Pyurvate Transaminase value (IU/L) changes before and after pre-medication and statistical comparison in both groups

Group	Mean value		% Age	SD±	SE±	t	P
	B.P.M.	A.P.M.	Increased/Decreased				
I (S.G.)	23.2	26	12.1 %	8.98	2.84	1	>0.05
II (T.G.)	26.3	29.7	13 %	8.4	2.66	1.15	>0.05

(I) Standard group, (II) Trial group; B.P.M. (before pre-medication), A.P.M. (after pre-medication)

Statistical comparison of mean Serum Glutamate Oxaloacetate Transaminase value before and after pre-medication in between two groups

Group	SE ±	t	P	R
I and II	1	0.18	> 0.05	NS

(I) Standard group, (II) Trial Group

Table 4: Mean Alkaline Phosphatase (IU/l) value changes before and after pre-medication and statistical comparison in both groups

Group	Mean value		% Age	SD ±	SE ±	t	P
	B.P.M.	A.P.M.	Increased/Decreased				
I (S.G.)	102.7	102.7	0	13.17	4.17	0.017	> 0.05
II (T.G.)	96.9	105.8	9.18	10.6	3.35	2.6	> 0.05

(I) Standard group, (II) Trial group; B.P.M. (before pre-medication), A.P.M. (after pre-medication)

Statistical comparison of mean AlkalinePhosphatase value before and after pre-medication in between the two groups

Group	SE ±	t	P	R
I and II	2.47	3.49	< 0.001	S

(I) Standard group, (II) Trial group

Table 5: Mean Total Serum Bilirubin value (mg %) changes before and after pre-medication and statistical comparison in both groups

Group	Mean value		% Age	SD ±	SE ±	t	P
	B.P.M.	A.P.M.	Increased/Decreased				
I (S.G.)	0.79	0.86	8.86 %	0.13	0.04	1.5	> 0.05
II (T.G.)	0.83	0.91	9.64 %	0.36	0.11	0.6	> 0.05

(I) Standard group, (II) Trial group; B.P.M. (before pre-medication), A.P.M. (after pre-medication)

Statistical comparison of mean Total Serum Bilirubin values before and after pre-medication in between the two groups

Group	SE ±	t	P	R
I and II	0.015	0.67	> 0.05	NS

(I) Standard group, (II) Trial group

Table 6: Mean Blood Urea value (mg %) changes before and after pre-medication and statistical comparison in both groups

Group	Mean value		%Age	SD ±	SE ±	t	P
	B.P.M.	A.P.M.	Increased/Decreased				
I (S.G.)	21.2	29.7	40%	8.17	2.59	0.15	> 0.05
II (T.G.)	25.1	26.6	5.97%	2.75	0.87	1.7	> 0.001

(I) Standard group, (II) Trial group; B.P.M. (before pre-medication), A.P.M. (after pre-medication)

Statistical comparison of mean Blood Urea values before and after pre-medication in between the two groups

Group	SE ±	t	P	R
I and II	2.73	0.4	> 0.05	NS

(I) Standard group, (II) Trial group

Table 7: Mean Serum Creatinine value (mg %) changes before and after pre-medication and statistical comparison in both groups

Group	Mean value		% Age	SD ±	SE ±	t	P
	B.P.M.	A.P.M.	Increased/Decreased				
I (S.G.)	0.72	0.69	4.17	0.2	0.06	0.3	> 0.05
II (T.G.)	0.77	0.92	19.5	0.06	0.02	7.9	> 0.001

(I) Standard group, (II) Trial group; B.P.M. (before pre-medication), A.P.M. (after pre-medication)

Statistical comparison of mean Serum Creatinine value levels before and after pre-medication in between the two groups

Group	SE ±	T	P	R
I and II	0.09	1.44	> 0.05	NS

(I) Standard group, (II) Trial group

Discussion on Objective Variables – Biochemical Changes

Blood Sugar

Patients of standard group showed 14.28 % increase in blood sugar level after pre-medication (SD ± 24.98 SE ± 7.9, t 2.75, $p < 0.05$) and patient of trial group showed 12.73 % increase in blood sugar level after pre-medication (SD ± 2.99, SE ± 0.95, t 9.4, $p < 0.001$) (Table 1). When both the groups were analyzed statistically, (for mean blood sugar level changes before and after pre-medication), intergroup comparison showed insignificant statistical results ($p > 0.05$), revealing no marked rise of blood sugar level in both the groups.

Serum Glutamate Oxaloacetate Transaminase

Patients of standard group showed 32.64 % increase in Serum Glutamate Oxaloacetate Transaminase level after pre-medication (SD ± 492.03, SE ± 155.7, t .06, $p > 0.05$) and patients of trial group showed 10.06 % increase in Serum Glutamate Oxaloacetate Transaminase level after pre-medication (SD ± 5.8, SE ± 1.8, t 0.99, $p > 0.05$) **(**Table 2). When both groups were analyzed statistically (for mean Serum Glutamate Oxaloacetate Transaminase level changes before and after pre-medication) intergroup comparison showed insignificant statistical results ($p > 0.05$).

Serum Glutamate Pyurvate Transaminase

Patients of standard group showed 12.1 % increase in Serum Glutamate Pyurvate Transaminase level after pre-medication (SD ± 8.98, SE ± 2.84, t 1, $p > 0.05$) and patients of trial group showed 13 % increase in Serum Glutamate Pyurvate Transaminase level after pre-medication (SD ± 8.4, SE ± 2.66, t 1.15, $p > 0.05$) (Table 3). When both groups were analyzed statistically (for mean Serum Glutamate Pyurvate Transaminas level changes before and after pre-medication), inter group comparison showed insignificant statistical results ($p > 0.05$)

Alkaline Phosphatase

Patients of standard group showed no increase or decrease on Alkaline Phosphatase level after pre-medication (SD ± 13.17, SE ± 4.17, t 0. 017, $p > 0.05$) and patients of trial group showed 9.18 % increase in Alkaline Phosphatase level after pre-medication (SD ± 10.6, SE ± 3.35, t 2.6, $p > 0.05$) (Table 4). When both groups were analyzed statistically (for mean Alkaline Phosphatase level changes, before and after pre-medication), intergroup comparison showed significant statistical results, ($p < 0.001$) revealing the marked rise in Alkaline Phosphatase value in case of trial group.

Total Serum Bilirubin

Patients of standard group showed 8.86 % increase in Total Serum Bilirubin level after pre-medication (SD ± 0.13, SE ± 0.04, t 1.5, $p > 0.05$), and patients of trial group showed 9.64 % increase in Total Serum Bilirubin level after pre-medication (SD ± 0.36, SE ± 0.11, t 0.6, $p > 0.001$), (Table 5). When both groups were analyzed statistically (for mean Total Serum Bilirubin level changes before and after pre-medication), intergroup comparison showed insignificant statistical results ($p > 0.05$).

Blood urea

Patients of standard group showed 40 % increase in blood urea level after pre-medication (SD ± 8.17, SE ± 2.59, t 0.15, $p > 0.05$), and patients of trial group showed 5.97 % increase in blood urea level after pre-medication (SD ± 2.75, SE ± 0.87, t 1.7, $p > 0.001$), (Table 6). When both groups were analyzed statistically (for mean blood urea level changes before and after pre-medication), inter group comparison showed insignificant statistical results ($p > 0.05$).

Serum creatinine

Patients of standard group showed 4.17 % decrease in serum creatinine level, after pre-medication SD ± 0.2, SE ± 0.06, t 0.3, $p > 0.05$), where as patients of trial group showed 92 % increase in serum creatinine level after pre-medication (SD ± 0.06, SE ± 0.02, t 7.9, $p < 0.001$), (Table 7). When both the groups were analyzed statistically (for mean serum creatinine level changes before and after pre-medication), intergroup comparison showed insignificant statistical results ($p > 0.05$).

CONCLUSION

The effect of bio-chemical values e.g. Serum Glutamate Oxaloacetate Transaminase, Serum Glutamate Pyurvate Transaminase, Total Serum Bilirubin, Blood Sugar, Blood Urea, Serum Creatinine and Alkaline Phosphatase level all were slightly increased after pre-medication in both groups but on intergroup statistical comparison of mean increase in levels of (Serum Glutamate Oxaloacetate Transaminase, Serum Glutamate Pyurvate Transaminase, Total Serum Bilirubin, Blood Sugar, Blood Urea, Serum Creatinine) bio-chemical values after pre-medication in standard as well as trial group showed insignificant statistical changes. In case of Alkaline Phosphatase intergroup statistical comparison showed significant statistical changes. In trial group there were more cases of fracture than standard group and this Alkaline Phosphatase value increases in case of bone injury, as the isoenzyme Alkaline Phosphatase 2 (β - 1) is produced by bones from the tissue source osteoblast. This is the reason that osteoblastic activity increases during the healing phase of fracture and hence Alkaline Phosphatase value also increases.

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