Research Article

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A CLINICAL EVALUATION OF KADAMBA (*ANTHOCEPHALUS INDICUS*) ON RESPIRATORY SYSTEM UNDER SPINAL ANESTHESIA

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ABSTRACT

Kadamba is described in Vednasthapana Mahakasaya in Charaka Samhita, so this study was to evaluate the efficacy of Kadamba[2] as analgesic and anti-inflammatory in Shalya Tantra department, Faculty of Ayurveda, IMS, BHU, Varanasi. This research work was done on 40 healthy patients. Which were divided into two groups included 20 patients with same age, height, and weight distribution. The patients were posted for lower abdominal surgeries and anorectal surgeries. Group I was pre medicated with kadamba ghanvati 1 gm (2 tablets) at 10 pm preoperative night and 90 min. before anesthesia and group II was pre medicated with tab. diclofenac sodium 50 mg at 10 pm preoperative night and 90 min. before anesthesia. It was observed that no alteration in respiration, mean blood pressure, pulse rate, oxygen saturation etc. and no post anesthesia sequels were observed. It shows that trial drug doesn't have side effects.

Keyword: Anesthesia, LSAB, MAP Kadamba**,** Premedication, Ghanstava.

INTRODUCTION

Sangyaharan[1-3] (Anesthesiology), the science based on the knowledge of Pharmacology, Biochemistry, Physiology, Biotechnology and Medicine and lastly the surgery. It is a science of natural phenomena, dealing with measurable, predictable and therefore, reproducible effect of drug on the function of cellular structure of animal and human.

A large number of indigenous drugs mentioned in Ayurvedic literature were experimentally screened on the animals and also studied clinically on the patients as pre anesthetic medicant[4] drug such as Brahmi, Jatamansi, Mandukparni, Shigru and Dashmool etc. The encouraging results of their studies prompted us to work on this line and a well-known Vednasthapaka[1] drug; Kadamba (*Anthocephalus indicus*) was selected to evaluate its analgesic and anti-inflammatory activity in practice of Sangyaharan as pre-medicate. The trial drug Kadamba was used in form of Ghanvati and compared with tab. Diclofenac sodium[5].

Various experimental and clinical studies have been done so far to assess the analgesic and anti-inflammatory action of some medicinal plants and indigenous compounds. In the present research work an indigenous drug Kadamba (*Anthocephalus indicus*) was selected to evaluate for its efficacy as an anti-inflammatory and analgesic, in the post-operative pain management under Lumber subarachnoid block.

Collection and preparation of Drug

The stem bark of Kadamba (*Anthocephalus indicus*) was collected from Ayurvedic Pharmacy, Institute of Medical Sciences, Banaras Hindu University, Varanasi and after confirming its validity by Dravya Guna department. The Ghansatva of Kadamba bark was prepared in ayurvedic pharmacy, I.M.S., BHU, Varanasi with the standard preparatory methods as mentioned in the texts of Ayurveda. For present research work drug was formulated in the form of vati of 500 mg.

Dose of Kadamba Ghanvati

Ghanvati 1 gm (2 tablets) at 10 p.m. of preoperative night and 1 gm (2 tablets) 90 min before the operation was the standard dose regime for the trial group.

Disintegration Time

The disintegration time of the prepared tablet at 37^0C of water was observed in the disintegration time machine. The time required for complete disintegration of tablet was found 34 minutes. The Kadamba Ghanvati was expected to dissolve in the stomach within their disintegration time.

Selection of the Patients

40 patients of either sex of A.S.A (American Society of Anesthesiologists) grade I and II undergoing, herniotomy with herniorrhaphy, hernioplasty, B.L.T.L., scrotoplasty, penoplasty, Primary threading, hemorrhoidectomy, appendectomy, hysterectomy, prostatectomy and Pilonidal sinus were selected from the Sangyaharan OPD, S.S. Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi. All patients of both groups were to undergo Lumber-Subarachnoid block (LSAB). The patients with deformities of spinal cord,

neurological and mental disturbances, hepatic diseases and renal diseases, cardiovascular diseases, hypersensitive to local anaesthetic, Diclofenac sodium and local infection were excluded. The study was conducted after proper written consent of individual patients explaining the methodology and aim of the study. Ethical approval was taken from the Institute ethical committee (Dean/2006-07/858, issued on 22.11.2006)

Grouping of the Patients

The selected 40 patients were randomly divided into two equal and identical groups i.e. group- I (control) and group-II (Trial) and were planned surgical procedures under spinal anesthesia.

Groups	No. of Patients	Premedication
Group I (Control)	20	1. Tab. Diclofenac 50 mg at 10 pm (previous night) and one hour before operation with an ounce of plain water orally. 2. Inj. Glycopyrrolate 0.2 mg I.M. 1 hour before the induction anesthesia
Group II (Trial)	20	1. Two tablets of Kadamba Ghanvati (500 mg each) at 10.00 pm (previous night) and one hours before operation with an ounce of plain water orally 2. Inj. Glycopyrrolate 0.2 mg IM 1 hour before the induction of anesthesia

Preoperative Preparation and Premeditation

All the patients were assessed thoroughly, and consent was taken about the proposed research work. Their age (years)**,** weight (kg), and vital status viz. pulse rate, blood pressure, respiratory rate, oxygen-saturation, end tidal CO_2 and oral temperature were recorded. General condition, physiological and psychological conditions were also recorded. The relevant routine investigations, which are essential prerequisite for the conduct of anesthesia, were evaluated and after complete satisfaction the grouping was done.

One hour after the scheduled medication, injection glycopyrrolate 0.2 mg was given by intramuscular route to the patient of both the groups, using uniformly the 24 G needle. Sixty minutes after premedication with injection glycopyrrolate, the patients were re-evaluated thoroughly regarding their vital signs, physiological and psychological conditions etc. Observations were recorded on the standard proforma for the study.

A patent intravenous line with Ringer lactate solution was maintained by identical size 18G intravenous cannula. After adequate preloading, the patients of were transferred to operation table. The induction of anesthesia was done by lumber subarachnoid block (LSAB) in lateral position (Knee-chest position) keeping their head on the pillow.

Now proper antiseptic dressing and draping of the Lumber area was done. Lumber puncture was done in all the cases of group- A by using 25 G spinal needle by midline approach. After ensuring free flow of CSF at the rate of 1 drop/sec inj. bupivacaine 0.5% (heavy) 3 ml was administered with bevel of needles maintained in cephalic position, and needle was withdrawn, and the area of skin prick was covered with sterile gauze piece. The patients were asked to change their posture to supine position with the help of assistant and adequate subarachnoid block was identified by absence of pinprick and touch sensation in operative area.[6]

Statistical Analysis

All the data collected viz. – Age, weight, height, blood pressure, pulse rate, respiratory rate, oral temperature, oxygen saturation, end tidal carbon dioxide, total surgical time, total duration of anesthesia, desirable and undesirable effect. First analgesic dose requirement time and post anesthetic sequel etc., were also recorded in a properly planned manner with the help of statistician on a master chart. The different statistical values as advocated for comparison e.g. mean, standard deviation (SD), applying unpaired t-test, t-value, standard error, p-value, z-value, using percentage of incidence and degree of freedom etc., were calculated under the guidance of expert statistician. The observations were noted and were presented in graphical way.

OBSERVATION AND RESULT

Table 1: Age, weight and Height

Group		Age (years) Mean ± SD	Weight (Kg) Mean ± SD	Height (cm) Mean ± SD
Group -I (Control)		41.75 ± 12.63	57.55 ± 7.02	164.80 ± 3.82
Group -II (Trial)		38.80 ± 15.30	54.50 ± 6.04	164.60 ± 4.76
Comparison between groups unpaired 't' test	T value	t = 0.66	t = 1.47	t = 0.15
	p-value	p > 0.05	P > 0.05	P > 0.05
Remark		NS	NS	NS

It is obvious from the above table that mean age, weight and height are statistically comparable and identical (p > 0.05) in the patients of both the groups.

Effect on Respiratory rate

Table 2A: The statistical comparison of mean respiratory rate per minute before premedication (A), after premedication (B), during subsequent anesthesia (C) and after recovery from anesthesia (D) between the two groups at corresponding time by applying student t-test and p-values and remarks are as follows

Group		Mean Respiratory Rate/min; (Mean ±SD)			
		Before premedication (A)	After premedication (B)	During subsequent anesthesia (C)	After recovery from anesthesia (D)
Group-I (Control)		16.75 ± 2.05	16.75 ± 1.62	17.50 ± 2.14	16.75 ± 1.42
Group-II (Trial)		16.90 ± 2.38	16.60 ± 1.96	17.40 ± 2.26	16.70 ± 1.63
Comparison between groups unpaired 't' test	t value	t = -0.21	t = 0.26	t = 0.14	t = 0.10
	p-value	p > 0.05	p > 0.05	p > 0.05	P > 0.05
Remark		NS	NS	NS	NS

Table 2A shows that mean respiratory rate/min in group - I at all the four level before premedication (A), after premedication (B) during subsequent anesthesia (C) and after recovery from anesthesia (D) is 16.75±2.05, 16.75±1.62 and 17.50±2.14, 16.75±1.42 respectively, while in group - II it is 16.90±2.38, 16.60±1.96 and 17.40± 2.26, 16.70± 1.63, respectively.

From Table 2A, it is observed that difference of mean respiratory rate per minute when compared in between group - I and group - II at corresponding four different timings; it is statistically insignificant and identical.

Table 2B: The statistical comparison of mean respiratory rate per minute within both groups before premedication (A), after premedication (B), during subsequent anesthesia (C) and after recovery from anesthesia (D), by mean±SD, paired t-test, p-values and remark are as follows

Comparison within the groups	Group I (Control)			Group II (Trial)		
	Mean ± SD	t-value p-value	Remark	Mean ± SD	t-value p-value	Remark
A vs. B	0.00 ± 1.55	t = 0.00 p > 0.05	NS	0.30 ± 2.27	t = 0.59 p > 0.05	NS
A vs. C	-0.75 ± 2.51	t = -1.34 p > 0.05	NS	-0.50 ± 3.17	t = -0.71 p > 0.05	NS
A vs. D	0.00 ± 1.52	t = 0.00 p > 0.05	NS	0.20 ± 3.03	t = 0.29 p > 0.05	NS

From Table 2B, it is observed that changes in respiratory rate are insignificant in both groups at the levels of before premedication vs. after premedication, before premedication vs. during subsequent anesthesia and before premedication vs. after recovery from anesthesia

Effect on oxygen saturation

Table 3A: The statistical comparison of difference in SPO2 percentage between the two groups at corresponding time i.e. before premedication (A), after premedication (B), during subsequent anesthesia (C), after recovery from anesthesia (D), by applying student t-test, p-values and remarks are as follows

Group		Mean oxygen saturation (%) (Mean ±SD)			
		Before premedication (A)	After premedication (B)	During subsequent anesthesia (C)	After recovery from anesthesia (D)
Group-I (Control)		99.00 ± 1.17	98.95 ± 0.94	99.00 ± 1.03	98.85 ± 1.14
Group-II (Trial)		98.90 ± 0.79	99.10 ± 0.79	99.25 ± 0.79	99.20 ± 0.83
Comparison between group unpaired 't' test	t value	t = 0.32	t = -0.55	t = -0.86	t = -1.11
	p-value	p > 0.05	P > 0.05	p > 0.05	P > 0.05
Remark		NS	NS	NS	NS

From Table 3A, it can be observed that mean SPO2 percentage in group - I, before and after premedication was 99.00±1.17 and 98.95±0.94, respectively while in group - II, it was 98.90±0.79 and 99.10±0.79, respectively. Again, mean SPO2 percentage in group - I during subsequent anesthesia and after recovery from anesthesia was 99.00±1.03 and 98.85±1.14 while in group - II it was 99.25±0.79 and 99.20±0.83 respectively.

From Table 3A, it is observed that difference of mean SPO2 percentage when compared between group - I and group - II at corresponding four different timings it is insignificant.

Table 3B: Statistical comparison of difference in the mean SPO2 percentage before premedication (A), after premedication (B), during subsequent anesthesia (C), and after recovery from anesthesia (D), within the groups by applying paired t-test, p-values and remarks are as follows

Comparison within the groups	Group A I (Control)			Group A II (Trial)		
	Mean ± SD	t-value p-value	Remark	Mean ± SD	t-value p-value	Remark
A vs. B	0.05 ± 0.88	t = 0.25 p > 0.05	NS	-0.20 ± 1.10	t = -0.81 p > 0.05	NS
A vs. C	0.00 ± 1.33	t = 0.00 p > 0.05	NS	0.35 ± 1.08	t = -1.44 p > 0.05	NS
A vs. D	0.15 ± 1.46	t = 0.46 p > 0.05	NS	-0.30 ± 1.12	t = -1.19 p > 0.05	NS

From Table 3B it is observed that difference of SPO_2 percentage at the level of before premedication and after premedication is insignificant in group - I and also in group - II and difference of mean SPO_2 before premedication, during subsequent anesthesia and after recovery from of anesthesia is insignificant in both groups.

Effect on end tidal carbon dioxide ($ETCO_2$)

Table 4A: The statistical comparison of difference of mean $ETCO_2$ in mmHg, between the two groups at corresponding time i.e. before premedication (A), after premedication (B), during subsequent anesthesia (C), after recovery from anesthesia (D), by applying student t-test, p-values and remarks are as follows

Group		Mean ETCO2 (mmHg); (Mean ± SD)			
		Before premedication (A)	After premedication (B)	During subsequent anesthesia (C)	After recovery from anesthesia (D)
Group -I (Control)		30.70 ± 2.27	30.70 ± 1.63	30.70 ± 1.87	31.10 ± 1.77
Group -II (Trial)		30.80 ± 1.51	30.90 ± 1.37	30.60 ± 3.25	30.90 ± 1.89
Comparison between groups unpaired 't' test	T value	t = -0.16	t = -0.39	t = 0.12	t = 0.35
	p-value	p > 0.05	p > 0.05	p > 0.05	P > 0.05
Remark		NS	NS	NS	NS

From Table 4A, it can be observed that mean $ETCO_2$ (mmHg) in group-I, before and after premedication was 30.70±2.27 and 30.70±1.63, respectively while in group - II, it was 30.80±1.51 and 30.90±1.37 respectively. Again, mean $ETCO_2$ (mmHg) in group - I during subsequent anesthesia and after recovery from anesthesia was 30.70±1.87 and 31.10 ±1.77 while in group - II it was 30.60±3.25 and 30.90±1.89 respectively.

From Table 4A, it is observed that difference of mean $ETCO_2$ (mmHg) when compared in between group - I and group - II at corresponding four different timings it is insignificant.

Table 4B: Statistical comparison of difference in the mean $ETCO_2$ (mmHg) before premedication (A), after premedication (B), during subsequent anesthesia (C), and after recovery from anesthesia (D), within the groups by applying paired t-test, p-values and remarks are as follows

Comparison within the groups	Group -I (Control)			Group - II (Trial)		
	Mean ± SD	t-value p-value	Remark	Mean ± SD	t-value p-value	Remark
A vs. B	0.00 ± 1.71	t = 0.00 p > 0.05	NS	-0.10 ± 1.88	t = -0.24 p > 0.05	NS
A vs. C	0.00 ± 2.24	t = 0.00 p > 0.05	NS	0.20 ± 3.66	t = 0.24 p > 0.05	NS
A vs. D	-0.40 ± 2.94	t = -0.61 p > 0.05	NS	0.10 ± 2.93	t = -0.15 p > 0.05	NS

From Table 4B, it is observed that difference of mean $ETCO_2$ (mmHg), at the level of before premedication and after premedication and before premedication, during subsequent anesthesia and before premedication and after recovery from anesthesia is insignificant in group - I and group - II.

DISCUSSION

The patients of all groups had similar age, height, weight. It was observed that changes in Respiratory rate, SpO2, EtCO2 between the groups at different level was insignificant and within the group at different level was almost similar. So this can be explained that there was no alteration in respiratory system of patients of all the groups. It means that the trial and control drugs do not produce any unwanted effect on respiratory system. Kadamba is described as vednasthapak dravya in Ayurvedic texts and it can be used in inflammatory painful condition without any untoward effects and post anesthesia sequels.

CONCLUSION

The clinical assessment of the present study was made under following parameters: Evaluation of psycho-physiological effect on the patients before and after premedication, effects during the course of subsequent anesthesia, observation during immediate postoperative recovery period. This can be explained that there was no alteration in respiratory system of patients of all the groups. It means that trial and control drugs do not produce any side effect on respiratory system. Kadamba is described as an important drug under vednasthapana mahakasaya[3] in Ayurvedic text possessing an anti-inflammatory and analgesic property[7]. On

these observations suggest that there was no any serious untoward effect of the both premedicants (control and trial) on respiratory system which can jeopardize to life of the patients**.**

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