



Research Article

www.ijrap.net (ISSN:2229-3566)



EVALUATION OF HAEMODYNAMIC EFFECT OF *ANTHOCEPHALUS INDICUS* (KADAMBA) IN POST OPERATIVE PAIN MANAGEMENT UNDER SPINAL ANESTHESIA

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Received on: 15/02/20 Accepted on: 15/05/20

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DOI: 10.7897/2277-4343.110495

ABSTRACT

Kadamba is described in Vedanasthapana Mahakashaya in Charaka Samhita, so this study was done to evaluate the efficacy of Kadamba as analgesic and anti-inflammatory in Shalya Tantra department, Faculty of Ayurveda, IMS, BHU and 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 premedicated with tab. diclofenac sodium 50 mg at 10 pm preoperative night and 90 min. before anesthesia and group II was pre medicated with Kadamba ghanvati 1 gm (2 tablets) at 10 pm preoperative night and 90 min. before anesthesia. It was observed that no alteration in Mean blood pressure, pulse rate, oxygen saturation etc. and no post anesthesia sequels were observed. It shows that trial drug doesn't have any side effects.

Keywords: Anaesthesia, LSAB, MBP, Kadamba, Premedication, Ghansatva.

INTRODUCTION

Sangyahaarana (Anesthesiology^{1,2}), 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 drugs³ mentioned in Ayurvedic literature were experimentally screened on the animals and also studied clinically on the patients as pre anesthetic medicant drug such as Brahmi⁴, Jatamansi⁵, Mandukparni, Shigru^{6,7} and Dashmool⁸ etc. The encouraging results of their studies prompted us to work on this line and a well-known Vednasthapaka⁹⁻¹¹ drug, Kadamba⁹⁻¹² (*Anthocephalus indicus*) was selected to evaluate its analgesic and anti-inflammatory activity in practice of Sangyahaarana as premedicant. The trial drug Kadamba was used in form of Ghanvati and compared with tab. Diclofenac sodium.

Various experimental¹³⁻¹⁴ 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 postoperative pain management under Lumber subarachnoid block.

MATERIALS AND METHOD

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. The yield of prepared semisolid Ghansatva was weighed and dose was calculated as per text. For medication facilities of the present research work drug was formulated in the form of vati (2 Tablets of 500 mg each) in the dose of 1 gm.

Dose of Kadamba Ghanvati

Ghanvati 1 gram (2 tablets of 500 mg) at 10 p.m. of previous night and 90 minutes before the operation was the standard dose regime for the trial group.

Disintegration Time

The disintegration time of the prepared tablet at 37°C of water was observed in the disintegration test and apparatus. The time required for complete disintegration of tablet was found to be 34 minutes. The Kadamba Ghanvati was expected to dissolve in the stomach within their disintegration time.

Selection of the Patients

In the present study 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., Skin grafting, scrotoplasty, penoplasty, Primary threading, Hemorrhoidectomy, appendectomy, Hysterectomy, prostatectomy and Pilonidal sinus were selected from the Sangyahaarana OPD, S.S. Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi. All patients of both groups

were to undergo Lumbar –Subarachnoid block (LSAB). The patients with deformities of spinal cord, neurological and mental disturbances, hepatic diseases and renal diseases, cardiovascular diseases, hypersensitive to local anesthetics, Diclofenac sodium and with 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 II (Trial) and were planned surgical procedures under spinal anaesthesia.

Groups	No. of Patients	Pre medication
Group I (Control)	20	1. Tab. Diclofenac 50 mg at 10 pm (previous night) and 90 min. before operation with an ounce of plain water orally. 2. Inj. Glycopyrrolate 0.2 mg I.M. 1 hour before the induction anaesthesia
Group II (Trial)	20	1. Two tablets of Kadamba Ghanvati (500 mg each) at 10.00 pm (previous night) and 90 min. before operation with an ounce of plain water orally 2. Inj. Glycopyrrolate 0.2 mg IM 1 hour before the induction of anaesthesia

Preoperative Preparation and Premedication

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 CO₂ 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 anaesthesia, were evaluated and after complete satisfaction the grouping was done.

One hour before 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 intravenous cannula (Veinflan – 18 G). After adequate preloading, the patients of were transferred to operation table. The induction of anaesthesia was done by lumbar Subarachnoid block (LSAB) in lateral position (Knee-chest position) keeping their head on the pillow.

Now proper antiseptic dressing and draping of the Lumbar area was done. Lumbar puncture was done in all the cases 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 regional block was identified by absence of pinprick and touch sensation in operative area.

Statistical Analysis

All the data collected viz. Age, weight, height, blood pressure, pulse rate, respiratory rate, oral temperature, oxygen saturation and end tidal carbon dioxide, total surgical time, total duration of anaesthesia, 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.

RESULT

Age, Weight and Height

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 Blood Pressure

Table 2A: The statistical comparison of difference in mean of mean blood pressure (mm Hg) between the groups at corresponding time i.e. before premedication (A), after premedication (B), during subsequent anaesthesia (C) and after recovery from anaesthesia (D), by applying student t-test, p-values and remarks

Group		Mean of MBP ± SD			
Group I (Control)		95.05 ± 7.99	95.30 ± 6.83	89.95 ± 9.41	94.75 ± 5.78
Group II (Trial)		95.35 ± 6.83	94.90 ± 5.45	86.75 ± 5.88	94.45 ± 5.07
Comparison between groups unpaired 't' test	t value	t = -0.13	t = 0.59	t = 1.29	t = 0.17
	p-value	p > 0.05	P > 0.05	p > 0.05	p > 0.05
Remark		NS	NS	NS	NS

Table 2A shows that mean of MBP in-group-I (Control) before and after premedication was 95.05 ± 7.99 and 95.30 ± 6.83 respectively, while in group - II (Trial) it was 95.35 ± 6.83 and 94.90 ± 5.45 respectively. Again, mean of MBP in group - I during subsequent course of anaesthesia and after recovery from anaesthesia was 89.95 ± 9.41 and 94.75 ± 5.78 while in group - II it was 86.75 ± 5.88 and 94.45 ± 5.07 respectively.

The above statistical comparison represents that difference in mean of mean blood pressure between group - I and group - II at corresponding four different timings are statistically insignificant.

Table 2B: The statistical comparison of mean of MBP (mmHg) before premedication (A), after premedication (B), during subsequent anaesthesia (C) and after recovery from anaesthesia (D), within the group by applying paired t-test, p-values and remarks

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	-2.50 ± 6.67	t = -0.17 p > 0.05	NS	0.45 ± 3.34	t = 0.60 p > 0.05	NS
A vs. C	5.10 ± 8.47	t = 2.69 p < 0.05	S	8.60 ± 4.90	t = 7.8 p > 0.05	S
A vs. B	0.30 ± 4.26	t = 0.31 p > 0.05	NS	0.90 ± 2.86	t = 1.41 p > 0.05	NS

From Table 2B it is observed that difference of MBP before premedication vs. after premedication, before premedication vs. after recovery from anaesthesia in both groups is insignificant but difference of MBP before premedication vs. during subsequent anaesthesia is significant in both the groups.

Effect on Pulse Rate

Table 3A: The statistical comparison of difference of mean pulse rate/min, between the two groups at corresponding time i.e. before premedication (A), after premedication (B), during subsequent anaesthesia (C), after recovery from anaesthesia (D), by applying student t-test, p-values and remarks

Group		Mean Pulse Rate/min; (Mean ± SD)			
Group I (Control)		79.30 ± 8.37	89.70 ± 8.49	83.25 ± 8.85	78.50 ± 7.04
Group II (Trial)		80.20 ± 7.65	92.20 ± 8.15	82.60 ± 9.20	78.70 ± 6.69
Comparison between groups unpaired 't' test	T value	t = -0.13	t = 0.59	t = 1.29	t = 0.17
	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 pulse rate/min in group - I, before and after premedication was 79.30 ± 8.37 and 89.7 ± 8.49 respectively while in group - II, it was 80.20 ± 7.65 and 92.20 ± 8.15 respectively. Again, mean pulse rate/min in group - I during subsequent anaesthesia and after recovery from anaesthesia was 83.25 ± 8.85 and 78.50 ± 7.04 while in group - II it was 82.60 ± 9.20 and 78.70 ± 6.69 respectively.

From Table 3A, it is observed that difference of mean pulse rate at corresponding four different timings of the study was identical and insignificant statistically, between group - I and group - II.

Table 3B: Statistical comparison of difference in the mean pulse rate/min before premedication (A), after premedication (B), during subsequent anaesthesia (C), and after recovery from anaesthesia (D), within the groups by applying paired t-test, p-values and remarks

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	-10.40 ± 3.58	t = -12.96 p < 0.05	S	-12.00 ± 3.37	t = -15.92 p < 0.05	S
A vs. C	-3.95 ± 8.78	t = -2.01 p > 0.05	NS	-2.40 ± 8.55	t = -1.26 p > 0.05	NS
A vs. D	0.80 ± 3.57	t = 1.00 p > 0.05	NS	1.50 ± 4.14	t = 1.62 p > 0.05	NS

From Table 3B, it is observed that difference of mean pulse rate, at the level of before premedication and after premedication is significant in group - I and also in group - II and difference of mean pulse rate before premedication and during subsequent anaesthesia and after recovery from anaesthesia is Insignificant in group - I and group - II.

Desirable Effects and Undesirable Effects

Table 4: Incidence of desirable effects and undesirable effects in patients of both groups after premedication

Effects	Incidence	Group-I (Control)		Group-II (Trial)		Z-value between Group-I vs. Group-II	Remarks
		No.	%	No.	%		
Sedation	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Apprehension	Present	5	25	3	15	z=0.79 p > 0.05	NS
	Absent	15	75	17	85		
Excitement	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Dizziness	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Nausea	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Vomiting	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		

Z-value is two proportions form independent groups.

Z value is calculated by

$$\frac{p_1 - p_2}{\sqrt{\left(\frac{p_1 q_1}{n_1} + \frac{p_2 q_2}{n_2}\right)}}$$

Where $p_1 = \frac{\text{Number of favourable case in control group}}{\text{Total cases in control group}}$; $q_1 = 1 - p_1$

$p_2 = \frac{\text{Number of favourable cases in trial group}}{\text{Total cases in Trial group}}$; $q_2 = 1 - p_2$

$n_1 = \text{Number of patients in group - I}$
 $n_2 = \text{Number of patients in group - II}$

The comparison between the group - I and group - II regarding sedation, apprehension and excitement is statistically insignificant. The statistical comparison of undesirable effects like dizziness, nausea, vomiting, in between group - I and group - II at the level of after premedication is insignificant.

Surgical Time and Duration of Anaesthesia

Table 5: Mean surgical time and mean duration of anaesthesia in group - I and group - II (expressed in minutes)

Parameters	Group - I (Control) (Mean ± SD)	Group - II (Trial) (Mean ± SD)	t-value	p-value	Remarks
Total Surgical Time (min)	40.50 ± 24.65	40.25 ± 18.09	t = 0.04	> 0.05	NS
Duration of Anaesthesia (min)	133.50 ± 5.64	132.75 ± 7.8	t = 0.35	> 0.05	NS

Mean surgical time in group - I and group - II expressed in minutes were 40.50 ± 24.65 and 40.25 ± 18.09, respectively. The statistical comparison between the groups is insignificant.

Mean duration of anaesthesia in minutes in group - I and group - II were 133.50 ± 5.64 and 132.75 ± 7.8 respectively. The statistical comparison between the groups is found to be insignificant.

Post Anaesthetic Sequel

Table 6: Incidence of post-anesthetic sequel observed between Group - I and Group - II

Side Effects	Incidence	Group - I (Control)		Group - II (Trial)		Z-value between Group - I vs. Group - II	Remarks
		No.	%	No.	%		
Sedation	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Nausea	Present	2	10	1	5	Z = 0.60 p > 0.05	NS
	Absent	18	90	19	95		
Vomiting	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Dizziness	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Dyspepsia	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Gastric Irritation	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Increased Peristalsis	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Hematemesis	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Melena	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Precipitation of Asthma	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Respiratory depression	Present	0	0	0	0	0	NS
	Absent	20	100	20	100		
Headache	Present	2	10	1	5	Z = 0.60 p > 0.05	NS
	Absent	18	90	19	95		
Backache	Present	3	15	3	15	Z = 0	NS
	Absent	17	85	17	85		

Nausea

Incidence of nausea was found 10% and 5% in patient of group - I and group - II respectively, which is also statistically insignificant.

Headache

Incidence of headache was found 10% and 5% in patient of group - I and group - II respectively. On statistical comparison, incidence of headache is insignificant.

Backache

The incidence of backache was found 15% in patients of both groups, which is statistically equal and identical.

Sedation, vomiting, dizziness, dyspepsia, gastric irritation, increased peristalsis, hematemesis, melena, precipitation of asthma, respiratory depression and other side effects were noted meticulously in both groups and was found to be absent in all the groups.

Requirement Time of 1st Dose of Analgesic

Table 7: The mean of the 1st analgesic dose requirement time (in minutes) of all patients in group - I and group - II were recorded and statistically compared

Groups	Mean \pm SD	t-value	p-value	Remark
Control Group - I	214.74 \pm 17.75	t = -1.92	p > 0.05	NS
Trial Group - II	228.33 \pm 24.97			

It is obvious from the above table that requirement of the first dose analgesic time in patients of both the groups was almost equal and identical time intervals the statistical comparison of first dose analgesic requirement time between the groups is insignificant.

DISCUSSION

The clinical assessment of the present study was made under following parameters - effect on the patients before and after premedication, effects during the course of subsequent anaesthesia and observation during immediate postoperative

recovery period. Alteration in the mean of MAP during the whole course of the observation compared within the group was found statistically insignificant except before premedication vs. during subsequent anaesthesia in the both groups. This mild fall in mean of MBP in patients of group - I and II during course of subsequent anaesthesia is well known effect of LSAB (lumbar sub arachnoid

block), which was almost identical in both the groups (I and II). The acceleration in the mean pulse rate in patients of all the groups (I and II) after premedication is a well-known pharmacological response of anti-cholinergic drug (Glycopyrrolate) used along with other (control and trial) premedicant. On the basis of the observation we are of the opinion that neither Diclofenac nor Kadamba Ghanvati showed any untoward response with known pharmacological action of Glycopyrrolate and stabilized CVS status of the patients. While observing the desirable and undesirable effects apprehension was found 25% and 15% in patients of group - I and group - II respectively and total mean surgical time was statistically insignificant in trial and control groups of patients. Similarly, mean anesthetic time was also statistically insignificant between the groups. The surgical and anaesthesia time was identical throughout the study in both groups. 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 cardiovascular system of patients of all the groups. It means that trial and control drugs do not produce any side effect on cardiovascular system Kadamba is described as an important drug under Vedanasthapana mahakashaya in Ayurvedic text possessing an anti-inflammatory and analgesic property these observations suggest that there was no any serious untoward effect of the both premedicants (control and trial) on cardiovascular system which can jeopardize to life of the patients.

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Cite this article as:

Vimal Kumar and K. K. Pandey. Evaluation of haemodynamic effect of *Anthocephalus indicus* (Kadamba) in Post operative pain management under Spinal anesthesia. Int. J. Res. Ayurveda Pharm. 2020;11(4):87-92 <http://dx.doi.org/10.7897/2277-4343.110495>

Source of support: Nil, Conflict of interest: None Declared

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