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Research Article

A CLINICAL STUDY ON THE MANAGEMENT OF PAIN IN CAESAREAN SECTION PATIENTS WITH *VRIHAT PANCHAMOOLA GHANASATWA*

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ABSTRACT

The management of post operative patients is a multi dimensional approach of treatment. Many common problems are developed during post operative period. Pain is one of the biggest problems amongst them. Therefore, an effective pain control is very essential to manage pain for post operative patients. There are lots of analgesics available in modern medical science. But they are causing side effects to the patients. Considering above problems faced by patients, a potent, safe and effective analgesic and well known *Vedanahara* and *Shoola prasamana* drug *Vrihat Panchamoola* was selected for this study. In this study 50 lower segment caesarean section patients (L.S.C.S) registered from labour room of *Prasutitantra* Department, S.S. Hospital, I.M.S, B.H.U, Varanasi (U.P) were selected randomly and divided in two equal groups. Group-I as trial and Group-II as control group. The trial patients are given 1000mg (two capsules of 500mg each) *Ghanasatwa* of *Vrihat Panchamoola* twice daily and the control group patients have given 50 mg Diclofenac Sodium twice daily after operation when bowel sound onset. After comparative study it has been found that, the trial drug *Vrihat Panchmoola Ghanasatwa* has produced good analgesic response during post operative pain management of L.S.C.S, patients.

KEYWORDS: Post Operative, Pain, Lower Segment Caesarean Section (L.S.C.S), *Vrihat Panchamoola*, *Ghanasatwa*, Analgesic.

INTRODUCTION

Ayurveda is the most ancient medical science, which gives preventive as well as curative measures with least adverse effects. Now-a-days surgical procedures have done profusely for several diseases. But, there are so many common problems developed during post operative period due to psychophysical and neurohumoral alterations caused by anesthesia and surgical trauma. Pain is the biggest problem of the patients during immediate post operative period. The acute pain is produced due to tissue trauma, inflammation and tissue hypoxia[1]. So management of pain is a matter of great concern for physicians as well as surgeons for operative patients. Post operative pain not only produces discomfort to the patients, but at the same times it also interprets many systemic functions of the body.

Though, many synthetic and semi-synthetic analgesics are being used frequently for post operative pain relief, but none of them are devoid of their well known untoward effects. Therefore a potent, safe and effective analgesic having least side effects, the well known *Vedanahara* and *Shoola prasamana* drug *Vrihat Panchamoola* (*Bilwa, Gambhari, Shyonaka, Patala* and *Agnimantha*)[2] was selected for this study in *Ghanasatwa* form.

In this study, 50 patients with narrow age, weight and height recommended for L.S.C.S operation were selected and randomly divided into two equal groups. Group-I was trial group and Group-II was control group. The patients of trial group has given 1000mg (two capsules of 500mg each) *Ghanasatwa* of *Vrihat Panchmoola* twice daily and the patients of control group has given Diclofenc sodium 50mg twice daily orally with an ounce of plain water. It was observed that, the trial drug *Vrihat Panchamoola Ghanasatwa* given orally has produced good analgesic

response during post operative period after onset of bowel sound in L.S.C.S. patients.

AIM AND OBJECTIVES

I. To find out a potent, safe, effective and economic analgesic herbal drug having least adverse effects.
II. To evaluate the analgesic effects of *Vrihat Panchamoola Ghanasatwa* in post operative L.S.C.S. patients.
III. To find out the adverse effects if any of the trial drug.
IV. Overall well being of the patients.

MATERIALS AND METHODS

For this study total 50 patients were registered from the labour room of *Prasutitantra* Department, S.S. Hospital, I.M.S, Banaras Hindu University, Varanasi during the year 2002-03. All patients were divided randomly into two equal and identical groups consisting of 25 each. Patients of Group-I were considered as trial group and advised to take *Vrihat Panchamoola Ghanasatwa* 1000mg twice daily with an ounce of plane water during post operative period after onset of bowel sound. Patients of Group-II were considered as control group and given tablet of Diclofenac sodium 50 mg orally in post operative period after onset of bowel sound.

After the medication the response was noted for local tissue inflammation, condition of wound, onset of bowel sound, intensity of pain etc. The numbers were assigned (0-4) to measure the intensity of pain. Zero denotes no discomfort and four denotes unbearable pain as shown under[3];

0 - No discomfort, complete at ease.

1 - Patient feeling a little discomfort.

2 - Patient staying still, eyes closed and avoiding movements.

3 - Patient's facial expressions strained.

4 - Patient writing sweating and distressed.

After completion of the study, the incidence of desirable and undesirable effects and incidences of adverse effects and nature of recovery were compared in both groups by Chi Square (x^2) and Fisher exact probability tests[4] whenever needed.

STUDY DESIGN

The patients registered from the labour room of *Prasuti* and *Streerog* department, S.S. Hospital, Institute of Medical Sciences, B.H.U, Varanasi during the year 2003 have selected irrespective of their Age, Weight, Height. Religion etc. All the selected patients were given their consent for this study.

OBSERVATION AND RESULTS

In this study 50 selected trial patients were divided in two groups i.e. Group-I (Trial group) and Group-II (Control group).

Table 1: Showing the number of patients in both groups and their drug regimen

Group	No. of Patients	Drug Regimen
I (Trial)	25	Two capsules (500mg each) twice daily of trial drug compound with an ounce of plain water given after L.S.C.S (after onset of bowel sound)
II (Control)	25	One tablet of Diclofenac Sodium 50mg given with ounce of water after L.S.C.S (after onset of bowel sound).

Table 2: Showing the mean post operative pain score (V.A.S) of both groups

Group	Before Treatment	After Treatment
I	5.72 ±1.38	2.53 ± 1.23
II	5.4± 0.76	2.49± 1.24

Table3: Statistical comparison of post operative pain score (V.A.S) within the groups

Group	Before Treatment Vs After Treatment
I	t= 7.41 p<0.001 (Highly Significant)
II	t=9.7 p<0.001 (Highly Significant)

Table 4: Statistical comparison of post operative pain score (V.A.S) between the groups

Group	Before Treatment	After Treatment
I Vs II	t=0.8 p< 1 (Not Significant)	t=0.12 P < 1 (Not Significant)

Comments: The mean post operative pain score (V.A.S) before treatment and after treatment in patients of Group-I is 5.72 ± 1.38, 2.53± 1.23 and in Group-II is 5.4 ± 0.76, 2.49± 1.24 respectively. The statistical difference before treatment and after treatment within the groups is highly significant. However, the differences of pain score are statistically insignificant between the group comparisons.

Table 5: Showing the mean postoperative pain score (O.A.D) in patients of the groups

Group	Before Treatment	After Treatment
I	2.96 ± 0.45	1.39 ± 0.18
II	2.84 ± 0.37	1.30 ± 0.21

Table 6: Statistical comparison of post operative pain score (O.A.D) within the groups

Group	Before Treatment Vs After Treatment
I	t = 9.61 p < 0.001(Highly Significant)
II	t = 3.34 p < 0.01 (Highly Significant)

Table 7: Statistical comparison of post operative pain score (O.A.D) between the groups

Group	Before Treatment	After Treatment
I Vs II	t = 1.02 p < 0.05 (Not Significant)	t= 1.55 p < 0.05 (Not Significant)

Comments: The mean post operative pain score (O.A.D), before treatment and after treatment in patients of Group-I is 2.96 ± 0.45, 1.39 ± 0.18 and in Group II is 2.84 ± 0.37, 1.30 ± 0, 21 respectively. The statistical difference before treatment and after treatment within the group is highly significant. However between the groups it is insignificant.

Table 8: Showing the mean time required (Hrs) for 1st and 2nd dose analgesic

Group	1st dose required time (Hrs)	2nd dose required time(Hrs)
I	23.5 ± 6.13	32.24 ± 5.95
II	23.36 ± 5.66	33.32 ± 6.33

Table 9: Statistical comparison of time required for 1st and 2nd dose analgesic between the groups

Group	1st dose required time (Hrs)	2nd dose required time (Hrs)
I Vs II	t = 0.11 p < 1 (Not Significant)	t= 0.63 p < 1 (Not Significant)

Comments: The mean 1st and 2nd dose analgesic requirement time in patients of group I is 23.5 ± 6.13, 32.24 ± 5.95 and in group-II is 23.36 ± 5.66, 33.32 ± 6.33 respectively. The statistical difference between the groups is insignificant.

Table 10: Showing the adverse effects of the trial drug compound and control drug in patients of both groups

Group	Nausea	Vomiting	Diarrhea	Gastric irritation
I	Nil	Nil	Nil	Nil
II	4 (16%)	2 (8%)	1 (4%)	2 (8%)

Comments: The above table shows that the trial drug compound has almost no adverse effects, whereas some patients under control drug complained nausea, vomiting, diarrhea and gastric irritation; which is well known and no significant relevance.

Table 11: Showing the condition of wound in patients of both groups

Group	Inflammation	Color	Discharge Present
		Normal Reddish	Present
I	1(4%)	24 (96%) 1(4%)	-
II	2 (8%)	23(92%) 2(8%)	-

From the above table it is observed that none of the patients have shown any wound complication. However the inflammation and reddish color of wound was observed in 4 to 8% patients of both groups, which is almost identical and not clinically serious.

Table 12: Showing the mean of total hospital stay (in days) in both groups

Group	Mean number of days ± S.D.
I	8.8 ± 0.5
II	8.84 ± 0.7

Table 13: Statistical comparison between both groups

Group	No. of days
I Vs II	t = 0.25 p < 1 (Not significant)

Comments: The mean of total hospital stay of both groups are 8.8 ± 0.5 and 8.84 ± 0.7. The difference of total hospital stay between the groups is not statistically significant.

DISCUSSION

The post operative pain is the extraordinary complex sensation of afferent nociceptive stimulation and stimulation of higher centers. In post operative period degree of discomfort due to pain varies with patient to patient. The site of operation is also important factor to determine the severity of post operative pain. It has been also assumed that age, gender and body weight are important factors in pain perception and responds to analgesic drugs.

Despite of many advances in the field of pharmacology, pain during post operative period has always been a global problem in the field of surgery. Pain itself not only produces distress to the patient during post operative periods affecting the physical and psychological harmony but also

influences psychological and neurohumoral variations. Morphine and its derivatives have been used in regular practice to pacify the pain of different origin. The use of synthetic and semi-synthetic preparations no doubt significantly reduces the pain, but no one can deny to experience their well known on towards effects i.e. Respiratory depression, emesis, constipation, loss of appetite and addiction etc. Therefore, post operative pain relief remains as a great concern till date.

A thorough research has been made in the texts of *Ayurveda* to evaluate some effective, potent and safe analgesic drugs for the post operative pain relief. The pioneers of *Ayurveda* have advocated many analgesic drugs under *Vedana shamaka* and *Vatahara* groups. For this clinical trial, drugs of *Vrihat Panchamoola* (*Bilva*, *Gambhari*, *Shyonaka*, *Patala* & *Agnimantha*) were selected and used in form of *Ghanasatwa*. The compound mixture of these five drugs was filled in capsule, containing 500mg in each capsule and given two capsules twice a day and found satisfactory, safe and good analgesic effect on post operative management in patients of lower segment caesarean section. The trial drug compound has almost identical analgesic properties with tablet Diclofenac Sodium used for post operative pain management.

CONCLUSION

On the basis of above observations and discussions it can be concluded the whole clinical trial as follows:

i) The trial drug compound *Vrihat Panchamoola* (*Bilwa*, *Gambhari, Shyonaka, Patala* and *Agnimantha*) in the form of *Ghanasatwa* given orally, produces good analgesic response during post operative period in L.S.C.S. patients.

ii) The trial drug compound is capable to minimize the post operative pain and found almost identical as compared to Diclofenac Sodium in terms of pain relief and duration of action.

iii) The trial drug compound did not show any cardio-vascular and respiratory depression at any stage of whole observation.

iv) The trial drug compound *Vrihat Panchamoola* did not show any significant untoward effect during post operative period.

v) *Vatashamaka*, *Vedanahara* and *Shoola prasamana* properties of the trial drug compound have kept the better wound condition and good analgesic action post operatively.

Thus in nut shell, this can be concluded that the trial drug compound can be used for the better post operative management as a potent analgesic, anti inflammatory and anti phlogogenic agent in patients where oral medication is allowed post operatively. An indigenous analgesic drug is the need of the millennium. Hence, it is required to explore more comprehensive observation and investigations to reach the final conclusion.

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