CAPSULE "SUJAT" FOR COMPREHENSIVE ANTENATAL CARE AND PREVENTION OF PREGNANCY INDUCED HYPERTENSION

Laxmi Bhosale, D Padia, Harish Malhotra,Deepti Thakkar, HS Palep, KM Algotar
Dept. of Obst. and Gynaecology, St. Georges Hospital and JJ Hospital, Mumbai.

INTRODUCTION

Comprehensive ANC care should ensure a good fetal wt. at birth. Birth wt. is not only the indicator of the health of the new born, but also predictive of the future health of the child. Low birth wt. babies are prone to suffer from DM hypertension, coronary vascular disorders in their later life.

Hypertensive disorders in pregnancy is a universally common disease. How pregnancy induces and aggravates hypertension is still not understood fully. The incidence of pregnancy induced hypertension (PIH) in India ranges from 5-15%.

In Primi's 16%

Multi's 7%

It causes IUGR leading to low birth weights. It increases the maternal mortality by 10-15% and the perinatal mortality and morbidity by 15 to 25%.

PATHOPHYSIOLOGY

The most important determinants of blood pressure are

1.Cardiac output

2.Peripheral vascular resistance (PVR)

Despite the increase in the cardiac output, there is a relative decrease in the BP due to the decrease in PVR during pregnancy.

This decrease is brought out by

(i)attenuated response to vasopressors

(ii)decrease in the ratio of PGI_2/TXA_2 and antioxidants/lipid peroxidases.

(iii)changes in the local factors like nitric oxides, endothelins.

There is an accumulated evidence which states that abnormal placentation is one of the initial events leading to this disease. The main feature is inadequate trophoblastic invasion of maternal spiral arterioles. Therefore the arteries retain their musculoelastic walls and thus respond to the vasoconstrictors produced e.g. leukotrienes and lipid peroxidases.

The other factors leading to the vasospasm are, immune complexes, genetic predisposition, dietary deficiency of Ca, Mg vasoactive compounds and endothelial cell injury. A study also indicates that there is a deficiency of antioxidants in patients with pregnancy induced hypertension.

The important vasodilators are PGI_2 and NO. A deficiency of these can lead to PIH. The endothelium of the blood vessels is the site of formation of NO + PGI_2. Endothelial cell damage leads to imbalance between vasodilators and vasoconstrictors leading to PIH.

Essential fatty acid GLA (Gamma Linolenic acid) is known to produce PGI2 in preference to TXA_2.

Mg supplementation is known to help Ca metabolism; Ca deficiency is known to be one of the causative factors of PIH.

Antioxidant supplementation also helps in preventing PIH by preventing placental peroxides leading to endothelial cell damage.

Nutrition and immunity are interlinked. Immunology has pivotal role in final outcome of pregnancy. Rasayana ingredients in Sujat help in modulating various immune processes at placental level. Therefore Sujat formulation which provides, all the above mentioned factors is expected to prevent PIH and ensure a good foetal outcome.

Its contents

Asparagus Racemosus	Essential aminoacids Fatty acids
Ipomoea Digitata	Starch and Mucilage
Trapa Bispinosa	
Embellica Officianale	Vit. C in buffered state (an excellent oxidant)
Trapa Bispinosa	Magnesium
Glycerhiza Glabra Sida Cordifolia	Potassium nitrate, Ca^{++}, Flavanoids very good NO donors
Withania Somnifera	Iron
Hemidesmus Indicum	Essential oil with antimicrobial action in GIT
Tribulis Terrestris	Increases GFR without electrolyte imbalance, contains 6 Essentialamino acids; also K^+ nitrate
Sida Cordifolia	Special anticonvulsant action and antipyretic action.
Glycerrhiza Glabra	Produces interferons Raises immunity, antiviral activity, Platelet activation factor inhibited. Inhibits myelosuppression actionof endotoxins e.g. liposaccharideendotoxin of *E. Coli*. It is a best free radical scavenger.
Asparagus Racemosus	Potent anti oxytocic Anti ADH activity. Prolactin Secretion increased.

To prove the efficiency or otherwise of the drug, a controlled trial consisting of 905 pts was done at Dept. of Obst. and Gyn., St. George's Hosp., Grant Medical College, Mumbai.

The study was carried over a period of 12 months from Dec. 97 to Nov. 98. There were 328 cases studied where cap. Sujat was given twice a day as soon as they got registered for antenatal care.

577 cases were in the control group who did not receive Sujat, but received routine antenatal care.

All these patients were followed up in the OPD and the indoor till they delivered and went home. Patient's BP, urine, proteinuria and wt. were checked. Mode of delivery and labour outcome was studied in all the cases and the results were analysed in 2 groups, in terms of incidence of PIH; mode of delivery; foetal wt. perinatal morbidity and mortality.

Statistical analysis of the study was made to find out the significant difference between the groups treated with Sujat and the control group. In this study Chi square (X^2) test was used.

X^2= å(0-E)2/E

O = Observed value, E = Expected value

RESULTS

The Table 1 shows that 84.4% of total cases in Sujat treatment group was in the age group of 21-31 years as compared to 79.9% in the control group which is almost same and difference between these two percentage was not significant.

TABLE 1

Age distribution in both groups which are identical

Age group in years	Sujat		Control	
	No.	%	No.	%
< 20 years	33	10.1	96	16.6
21-29 years	230	70.1	382	66.2
30-34 years	47	14.3	79	13.7
> 35 years	18	5.5	20	3.5
Total	328	100	577	100

P > 0.05 Not Significant

3.35% of total cases in Sujat treatment group developed PIH problems which is significantly low as compared to 10.39% in control group 81.8% of total cases (Table 2).

The Table 3 shows that in Sujat treatment PIH development amongst 72.7% were after the 36 weeks of gestation as compared to in control group out of total PIH cases 55% had problem before the 36 weeks of gestation.

TABLE 2

The percentage and severity of PIH. Sujat group showed significant reduction in the incidence and severity of PIH

Severity	Sujat		Control	
	No.	%	No.	%
Mild	9	81.8	32	53.3
Moderate	2	18.2	17	28.3
Severe	—	—	7	15.7
Eclampsia	—	—	4	6.7
Total	11	100	60	100%
% of PIH	3.35%		10.39%	

P < 0.001 Highly significant

TABLE 3

Significant difference in the development of PIH in relation to gestational period. Sujat group PIH developed only after 36 weeks

Gestation period inWk 3	Sujat		Control	
	No.	%	No.	%
28-32 wk	1	9.09%	9	15.0%
32-36 wk	2	18.18%	24	40.0%
> 36 wk	8	72.72%	27	45.0%
Total	11	99.99%	60	100%

P < 0.05 significant

Percentage of PIH at Primi and Multi in the control Registered cases were 13.33% and 8.16% respectively as compared to 4.87% and 2.43% in Sujat treatment group which is significantly low.

TABLE 4

Percentage of PIH according to parity was not significant

Groups	**Primi**		**Multi**	
	Total Cases	PIH	Total Cases	PIH
Sujat	123	6 (4.87%)	205	5 (2.43%)
Control	195	26 (13.33%)	392	32 (8.16%)

P < 0.01 Significant

Average birth weight of the babies in Sujat Group was 2.82 Kg which is significantly higher as compared to 2.58 kg in Control Group (Table 5).

The Table 6 shows that only 25.6% of total

TABLE 5

The comparison of average birth weight between Sujat and Control group. A significant increase of 115 gms wt. in Sujat group is the highlight of the study

Group	Average birth weight (Mean ± SD)
Sujat	2.82 kg ± 0.44 kg
Control	2.58 kg ± 0.55 kg

P < 0.001 Highly significant

TABLE 6

Significant drops of number of babies weighing < 2.5 kg groups				
Weight in kg.	Sujat		Control	
	No	%	No.	%
< 2.5 Kg	84	25.60%	207	35.9%
2.5 to 3 Kg	167	50.9%	293	50.8%
3.01 and above	77	23.5%	77	13.3%
Total	328	99.98%	577	99.98%

P < 0.05 Significant

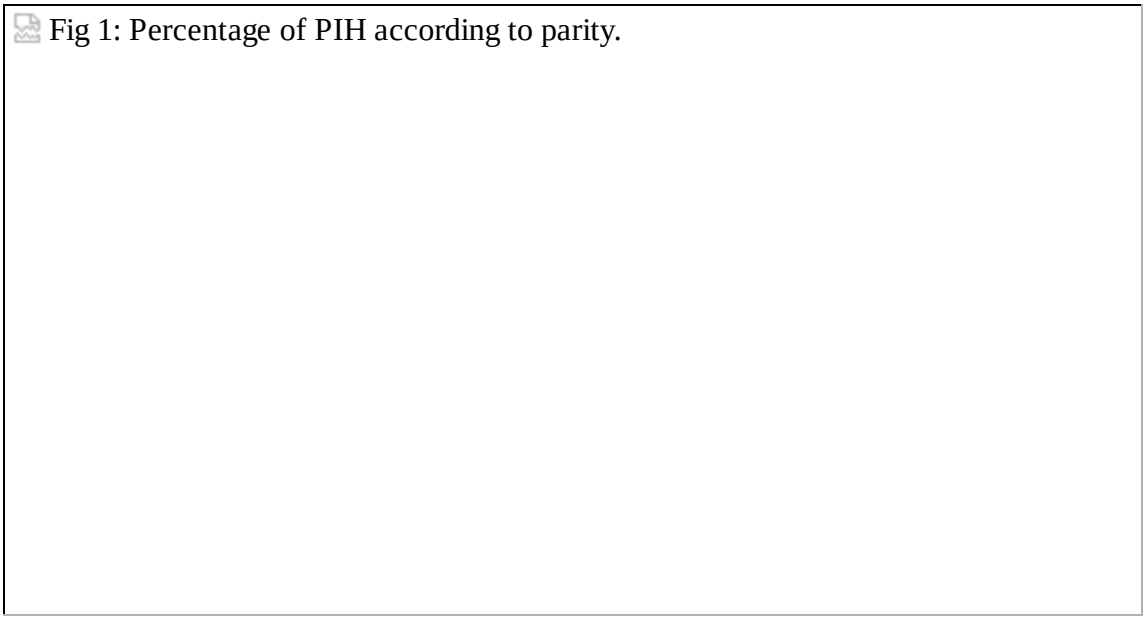

Fig 1

Percentage of PIH according to parity.

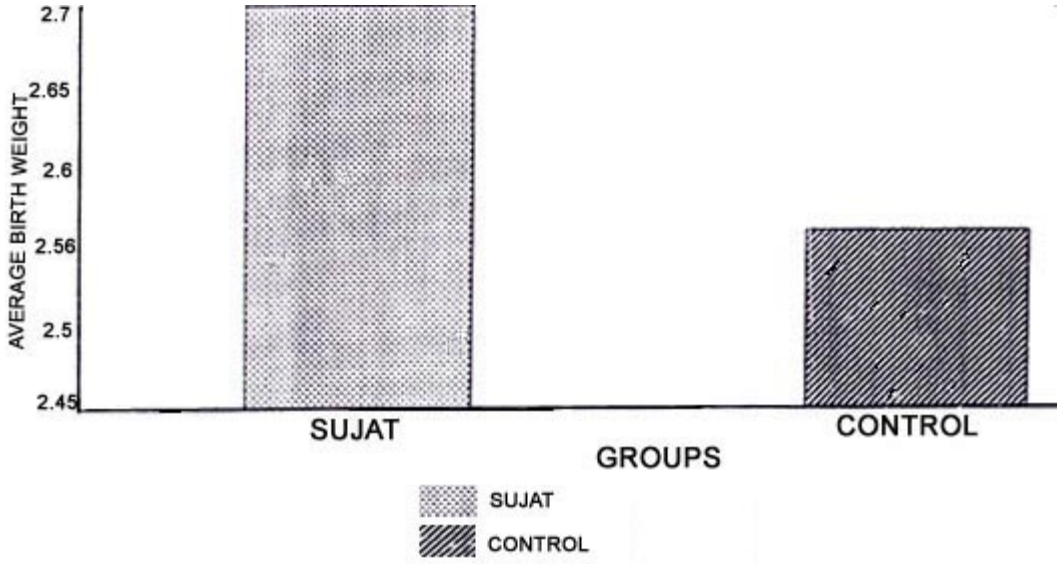

Fig 2

Comparison of average birth weight between sujat and control group

women in Sujat treatment had less than 2.5 kg. Foetal weight which is significantly less as compared to 35.9% in control registered cases.

Profile of field morbidity was more amongst the control registered cases i.e. 23.88% as compared to only 12.78% in Sujat treatment group which is significantly less (Table 7).

Number of babies required intensive care in Sujat group were significantly less as compared to 11.95% in control.

TABLE 7

Mode of delivery was not significantly different in both groups

Morbidity	Sujat		Control	
	No.	%	No.	%
No. of babiesin NICU	22	6.70%	69	11.95%
Still birth with FSB and MSB	3	0.91%	15	2.59%
Congenital anomaly	2	0.60%	3	0.51%
Pre-term deliveries	15	4.57%	51	8.83%
Total	42	12.78%	138	23.88%

P < 0.001 Highly Significant

The data below reveals that 82.6% and 81.10% of total cases had normal deliveries in Sujat and Treatment group respectively, which is almost same (Table 8).

TABLE 8

Foetal morbidity and perinatal mortality was significantly less in Sujat groups				
Mode of delivery	Sujat		Control	
	No.	%	No.	%
Normal	271	82.6	468	81.10
LSCS	41	12.5	81	14.00
Instrumental	16	4.9	28	4.9
Total	328	100	577	100

P > 0.05 Not significant

DISCUSSION

Various treatment modes known so far for prophylaxis of PIH are as follows:

1. *Calcium supplementation* : Many studies conducted world over have given contradictory results.

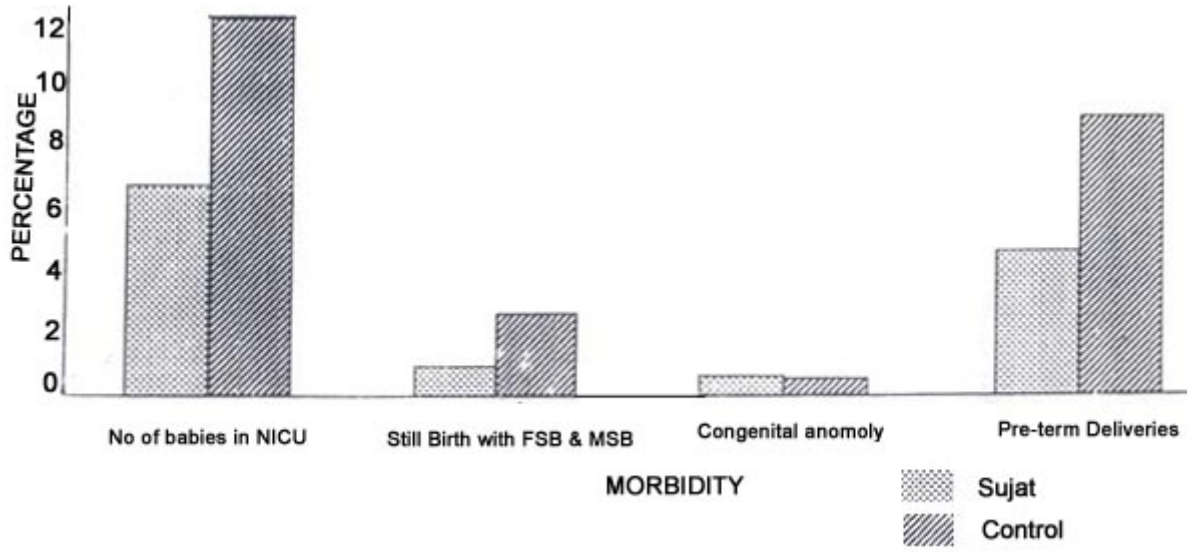

Fig 3

Profile of morbidity (foetal) in both the groups.

Table 9 : Percentage of PIH			
Study		**Total No. of Pts.**	**% PIH**
1.	Clasp Study 1994	9364 (4681)	S-19.7% C-22.2%
2.	Lancet : Low dose aspirin in prevention of PIH prevention of PIH and IUGR	(565) (477)	S-12.4% C-12.30%
3.	Sujat Prevention of PIH	460 (190) (270)	S-3.15% C-7.04%

2.*Low dose aspirin*: Aspirin is used to reduce the TXA2 by virtue of antiprostaglandin action. It is found to have lot of platelet related side effects like haemorrhages in the new born (we have compared our results with the published trials in Tables 9 and 10.

Sujat treatment goes on the basis of enhancing the endothelial cell activity without damaging platelets (as in the case of aspirin). It is a positive concept in contrast to low dose aspirin therapy.

Sujat is a blend of various factors viz. NO donors, antioxidants, essential amino acids (L arginine) essential fatty acids (GLA) Magnesium, Calcium and immuno modulators. Sujat formulation thus successfully helps in preventing PIH and pregnancy outcome.

CONCLUSION

Sujat is an efficient drug formulation to prevent PIH as well to enhance the foetal wt and foetal outcome. Prophylactic Sujat Therapy is an insurance to a comprehensive antenatal care and safe motherhood.

Table 10: Profile of average birth weight and perinatal death

	Study	Total no.of Pts.	Total no. Of Groups	Average Birth Weight (SD)	Perinatal Deaths
1.	Lancet (1990) June Doppler Study (USG) and Aspirin in recognition and prevention of PIH	100	S 48 C 52	2954 gms (852) 3068 gms (555)	1 IUFD (42 Wks) 2 IUD (25 Wks) (28 Wks) 1 NND (27 Wks)
2.	New England Journal of Medicine Use of aspirin to prevention of PIH	65	S 34 C 31	3037 gms 2706 gms	No neomatal deaths (NND) No neonatal deaths
3.	Clasp : The Lancet (1994) Low dose aspirin for prevention of PIH	8259	S 4123 C 4134	3024 gms (788) 2991 gms (810)	120 (2.7%) 136 (2.8%)
4.	Lancet 1993 Feb. Low dose aspirin in prevention and treatment of IUGR and PIH		S 565 C 477	2858 gms. 2847 gms	35.7 per 1000 birth 28.6 per 1000 birth
5.	Sujat : A drug for prevention of PIH	450	S 190 C 270	2739 gms (399.8) 2624 gms (470.6)	10.1 per 1000 births 21.92 per 1000 births

Key - S : Study, C : Control

REFERENCES

1. CLASP. Lancet March 12, 1994; 343 (8898) : 619-29.
2. Lancet I 1985; 840-42.
3. Benigua. NEJM 1989; 321 : 357-62.
4. Lancet 2 335-38, 975.
5. Lancet Feb. 20, 1988; (8582) : 410.
6. Br Med J 391 1277-78.
7. Lancet 1990; 335 : 1552-55.
8. JAMA 1988; 260 : 657-61.

9. J Indian Med Assoc Jan. 1994; 92 (6) : 188-91.
10. Bull Pan Am Health Organ 1991; 25 (2) : 109-A.
11. JAMA Nov. 6, 1996; 276 (17) : 1387.
12. Journal of Obst + Gynaecol June 1995; 21 (3) : 281-8.
13. Br J Obstel Gynaecol Feb. 1995; 102 (2) : 123-6.
14. Lancet Feb. 13, 1993; 341 (8842) : 396-400.
15. J of Obst and Gynaecol 1995; 86 (4) : 600-608.
16. J of Obst and Gynaecol Jan. 1988; 71 : 1.

To Section TOC