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"THE EFFECT OF PROPHYLACTIC INTRAVENOUS GLYCOPYRROLATE ON THE INCIDENCE OF HYPOTENSION AND VASOPRESSOR REQUIREMENT DURING SPINAL ANAESTHESIA FOR CAESAREAN SECTION."

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ABSTRACT:

INTROUCTION: Spinal anesthesia (SA) has become a popular technique for LSCS as it is advantageous being a quick, safe and a reliable option that also provides analgesia post-operatively. Hyperbaric drugs which are routinely used can produce very high blocks in pregnant women because of decreased volume and increased pressure of CSF due to engorged epidural veins which is a result of aorto-caval compression and high CSF pressure. Haemodynamic changes[1,2,3] like hypotension, Bradycardia were commonly associated complication with spinal-anaesthesia in obstetric parturients. For minimizing spinal-induced haemodynamic changes with anticholinergic drugs may be of interest. Anticholinergics like atropine and Glycopyrrolate are routinely used in anaesthesia for premedication. Atropine easily crosses placental barrier and blood-brain barrier as it has a tertiary amine structure. However, Glycopyrrolate having a structure of quaternary amine, limits its ability to cross these barriers. Hence Glycopyrrolate is the desired option for obstetric parturients

AIMS and OBJECTIVES: To study the haemodynamic stability, efficacy and other adverse effects of Glycopyrroate during spinal anaesthesia for caesarean delivery.

MATERIAL SOURCE:

All the partirients who are undergoing caesarean section divided in to 2 groups of 30 in each group G and Group C. They are included and excluded depending on their physical status and any contra indications to Spinal anaesthesia

Results: showed more stable haemodynamics in Group G showing Glycopyrrolate[5, 6, 7, 8] is better anticholinergic drug which does not cross placenta barrier.

Conclusion: Pre-treatment before administering spinal anaesthesia (SA) in pregnant women who are posted for elective caesarean sections with 0.2 mg of Glycopyrrolate in patients decreases the incidence of hypotension before the extraction of the neonate. Glycopyrrolate also reduces the incidence of Bradycardia.

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Key words: Spinal Anaesthesia, Glycopyrrolate, Ephedrine, hypotension, Bradycardia

INTRODUCTION

Spinal anaesthesia (SA) has become a popular technique for LSCS as it is advantageous being a quick, safe and a reliable option that also provides analgesia post-operatively. Traditionally hyperbaric drugs are used for spinal anaesthesia for LSCS – like hyperbaric 0.5% bupivacaine, as one can easily predict the movement of the given drug in the cerebrospinal fluid (CSF).

Haemodynamic changes[1,2] like hypotension, bradycardia were commonly associated complication with spinal-anaesthesia in obstetric parturients. Anticholinergics like atropine and Glycopyrrolate are routinely used in anaesthesia for premedication. Atropine easily crosses placental barrier and blood-brain barrier as it has a tertiary amine structure. However, Glycopyrrolate[5] having a structure of quaternary amine, limits its ability to cross these barriers. Hence Glycopyrrolate is the desired option for obstetric patient

AIMS AND OBJECTIVES

The influence of IV Glycopyrrolate 0.2 mg as a pre-medication drug during spinal anaesthesia with 2 ml 0.5% hyperbaric Bupivacaine, in pregnant women for elective Caesarean Section regarding -

Objective:

To study the haemodynamic stability, efficacy and other adverse effects of Glycopyrroate during spinal anaesthesia for caesarean delivery.

MATERIAL SOURCE:

Parturient of American Society of Anaesthesiologists (ASA) Physical status Class II, who were scheduled to undergo elective caesarean delivery under Sub Arachnoid Block (SAB), who fulfilled the inclusion criteria mentioned hereafter, at Government general hospital, Kurnool.

INCLUSION CRITERIA:

- Age between 18 – 35 years
- Height 150 – 170 cm
- Body mass index < 28 kg/m2
- Singleton pregnancy

EXCLUSION CRITERIA:

Parturient having contraindications to spinal anaesthesia, i.e, consent refusal, local infection, allergy to local anaesthetics, bleeding disorders, spinal deformity, severe congenital or acquired heart disease, hemorrhage or hypovolemic shock Parturient with complications of pregnancy like preeclampsia, gestational diabetes, placenta praevia Known sensitivity to the study drugs.

TYPE OF STUDY This is a prospective observer blinded, comparative study design using simple random sampling and shuffled closed sealed envelope technique

CHEMICALS USED: 0.5% Hyperbaric Bupivacaine, Inj.

Glycopyrrolate 0.2 mg, Inj. Ephedrine.

INSTRUMENTS REQUIRED: 25 G Quincke's Spinal Needle.

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METHDOLOGY

They were randomized allocated into two equal groups by simple random sampling using *shuffled closed sealed envelope technique*, namely Group G & C.

Group G – IV Glycopyrrolate 0.2 mg, 1 cc.

Group C – IV Normal saline 1 cc.

Pre Anaesthetic Evaluation (PAE) of all the pregnant women was done on the previous day with written-informed consent in their own vernacular language was taken. All parturients were explained about nil-per oral status of 6 hrs for solids and 2 hrs for clear liquids. After connecting multi-parameter monitors with Echocardiography, Non-Invasive Blood Pressure (NIBP), pulse-oximeter basal parameters were recorded. Group G parturient received IV Glycopyrrolate 0.2 mg (1 ml) followed by which spinal anaesthesia using 25 G Quincke needle with 2 ml 0.5% Hyperbaric Bupivacaine was given in sitting posture and immediately laid to supine posture with a wedge underneath the right buttock. Parturient in group C received IV normal saline 1 ml followed by which spinal anaesthesia was given using 2 ml 0.5% Hyperbaric Bupivacaine in sitting posture and laid immediately to supine posture with a wedge underneath the right buttock. Pin prick method with 25G needle with blunted tip was used to assess sensory block level achieve

DURATION: MARCH 2022- JULY 2023.

STATISTICAL ANALYSIS:

Data was entered into Microsoft excel data sheet. SPSS 22 version software was used for analysis. Categorical data was shown as frequencies and proportions. **Chi-square test** was used for qualitative data. Continuous data was represented as mean and standard deviation**.**

Independent t test was used to compare age, weight, height, body mass index (BMI), pulse-oximetry saturation, APGAR score between two groups.

RESULTS

Table No-1: Comparison of changes in Mean Pulse Rate with time between both groups

Time	Group G	Group C	t-value	p-value
Baseline	86.1 ± 7.11	84.9 ± 6.35	**0.690**	**0.493; NS**
1 minute	90.9 ± 6.88	93.9 ± 7.37	**1.623**	**0.109; NS**
3 minutes	96.5 ± 9.90	92.0 ±10.65	**1.695**	**0.095; NS**
5 minutes	105.1±11.56	101.3±12.08	**1.245**	**0.218; NS**
8 minutes	102.8±12.22	92.1 ± 10.79	**3.595**	**<0.001; S**
11 minutes	99.9 ± 12.68	89.7 ± 12.77	**3.105**	**0.003; S**
15 minutes	98.4 ± 12.93	91.5 ± 11.10	**2.218**	**0.031; S**
20 minutes	101.7±12.00	91.8 ± 11.07	**3.321**	**0.002; S**
25 minutes	97.6 ± 9.92	93.3 ± 6.86	**1.953**	**0.056; NS**
30 minutes	95.7 ± 10.23	90.3 ± 10.37	**2.030**	**0.047; S**
40 minutes	91.8 ± 10.89	90.1 ± 10.20	**0.624**	**0.535; NS**
50 minutes	90.9 ± 7.32	89.8 ± 10.26	**0.478**	**0.634; NS**
60 minutes	89.4 ± 9.95	88.5 ± 8.83	**0.371**	**0.712; NS**

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S = Significant; NS = Not significant

Mean pulse rate was shown to be significantly higher in group G (Glycopyrrolate group) compared to group C (IV Normal saline) from 8 minutes to 20 minutes and again at 30 minutes. Overall higher mean pulse rate (105.1 bpm) was seen in group G (Glycopyrrolate group) at 5th minute. In other time frames, difference between the groups was not significant.

Fig no 1: **Comparison of changes in Mean Pulse Rate with time between both groups**

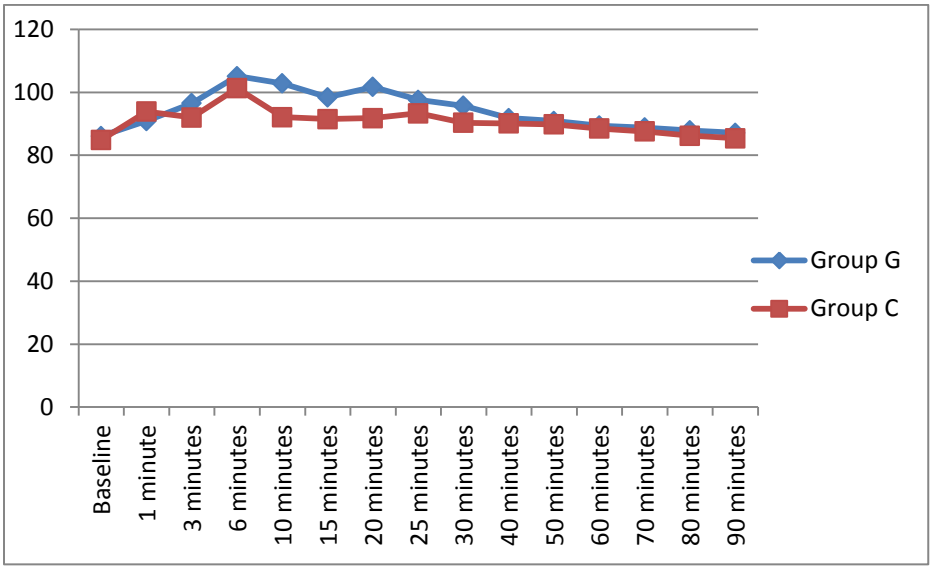

TABLE: 2 Comparison of groups by Incidence of Bradycardia

Incidence of Bradycardia	Group G (N=30)	Group C (N=30)	P value
At 3 minutes	0	1 (3.3%)	1.000; NS
At 11 minutes	0	1 (3.3%)	1.000; NS

In Group C, at 3rd minute and 11th minute one case was reported to have Bradycardia. But in Group G, none of the patients were reported to have Bradycardia at any time in follow up period. This difference in occurrence of bradycardia between groups was not significant statistically. (P> 0.05; Not Significant)

Fig No 2: Comparison of groups by Incidence of Bradycardia

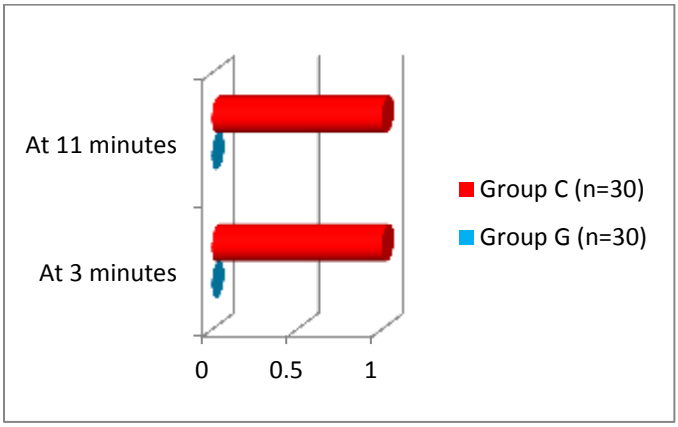

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Table no 3: Comparison of changes in Mean systolic blood pressure (SBP) with time between groups

Changes in SBP with time	Group G (mm of Hg)	Group C	t-value	P - value
Baseline	121.3 ± 11.71	119.0 ± 11.38	0.772	0.444; NS
1 minute	122.9 ± 9.47	122.5 ± 9.22	0.166	0.869; NS
3 minutes	121.6 ± 10.00	113.8 ±9.97	3.026	0.004; S
5 minutes	114.7 ± 10.13	103.5 ± 9.70	4.374	<0.001; S
8 minutes	110.1 ± 9.97	105.1 ± 9.47	1.992	0.051; NS
11 minutes	111.0 ± 10.99	106.7 ± 9.27	1.638	0.107; NS
15 minutes	112.2 ± 10.36	107.5 ± 9.90	1.797	0.078; NS
20 minutes	110.2 ± 11.61	105.5 ± 9.68	1.703	0.094; NS
25 minutes	109.1 ±10.67	105.8 ± 10.13	1.170	0.247; NS
30 minutes	111.5 ± 11.76	106.4 ± 9.97	1.812	0.075; NS
40 minutes	112.5 ± 10.88	108.8 ± 10.44	1.344	0.184; NS
50 minutes	113.8 ± 10.37	113.1 ± 10.33	0.262	0.794; NS
60 minutes	115.5 ±9.50	114.3 ± 10.08	0.475	0.637; NS
70 minutes	117.3 ± 11.52	116.1 ± 9.27	0.445	0.658; NS
80 minutes	119.3 ± 11.40	118.5 ± 11.55	0.270	0.788; NS
90 minutes	121.1 ± 11.00	120.1 ± 11.19	0.349	0.728; NS

S = Significant; NS = Not significant

Mean systolic blood pressure was significantly higher in group G compared to group C at 3 minutes and 5 minutes of post spinal anaesthesia induction. In remaining time periods, difference in mean systolic blood pressure was not significant between two groups. Highest mean SBP was recorded in group G at 1 minute and lowest mean SBP was recorded in group C at 5 minutes.

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Fig No 3: **Comparison of changes in Mean systolic blood pressure (SBP) with time between groups**

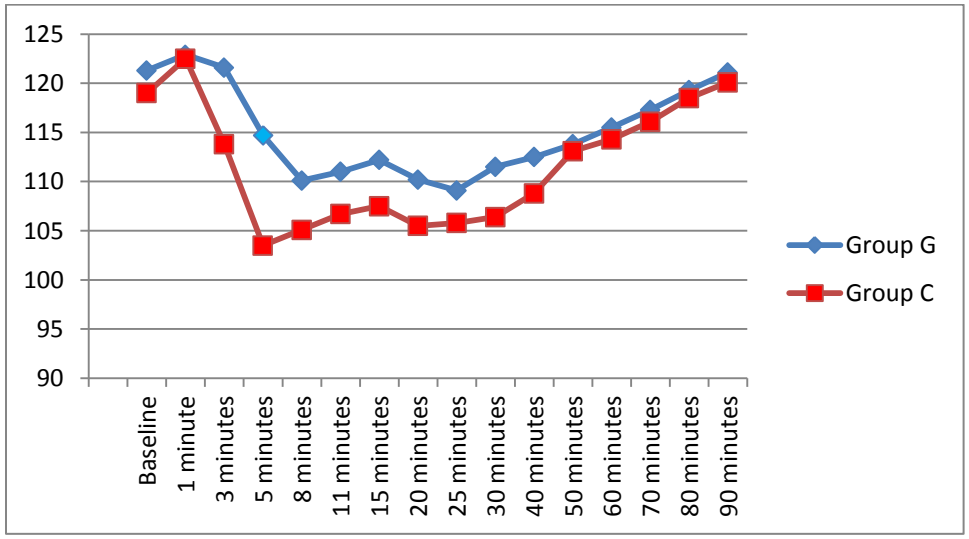

Table No 4: comparison of changes in Mean Diastolic Blood Pressure with time between both groups

Changes in DBP with time	Group G	Group C	t - value	p - value
base line	78.1±8.18	76.6 ± 8.87	0.681	0.499; NS
1 minute	78.9 ± 9.05	77.4 ± 10.50	0.593	0.556 NS
3 minutes	74.6 ± 7.72	68.5 ± 8.27	2.953	0.005; S
5 minutes	66.1 ± 10.60	62.1 ± 8.60	1.605	0. 114; NS
8 minutes	65.1± 8.42	64.3 ± 8.55	0.365	0.716; NS
11 minutes	65.7 ± 8.57	63.3 ± 8.04	1.119	0.268; NS
15 minutes	64.5 ± 8.00	64.1 ± 8.75	0.185	0.854; NS
20 minutes	63.1 ± 7.97	60.6 ± 9.07	1.134	0.261; NS
25 minutes	61.9 ± 8.48	61.3 ± 8.77	0.269	0.789; NS
30 minutes	63.6 ± 8.32	61.9 ± 9.32	0.745	0.459; NS
40 minutes	65.5 ± 9.43	64.9 ± 9.03	0.252	0.802; NS
50 minutes	65.9 ± 10.37	66.2 ± 10.31	0.112	0.911; NS
60 minutes	67.9 ± 8.33	69.0 ± 8.70	0.500	0.619; NS
70 minutes	69.4 ± 8.17	70.1 ± 8.21	0.331	0.742; NS
80 minutes	70.7 ± 8.19	71.3 ± 8.54	0.278	0.782; NS

S = Significant; NS = Not significant

Mean diastolic blood pressure was significantly higher in group G compared to group C at 3 minutes of post spinal anaesthesia induction. In remaining time periods, difference in mean diastolic blood pressure was not significant between two groups. Highest mean DBP was recorded in group G at 1 minute and lowest mean DBP was recorded in group C at 20 minutes.

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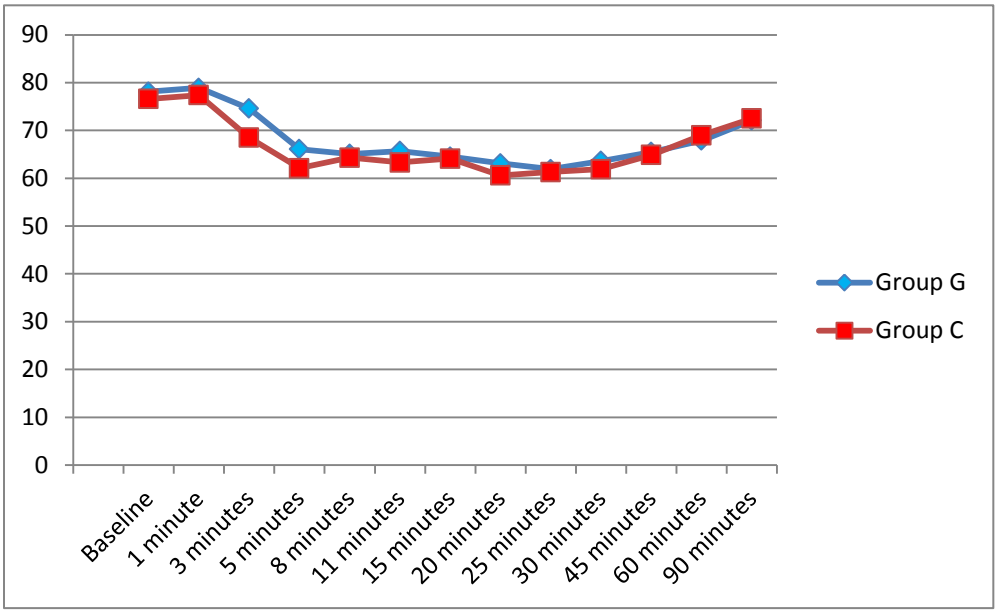
Fig No. 4: comparison of changes in Mean Diastolic Blood Pressure with time



Tabe no 5: Comparison of changes in Mean Arterial pressure (MAP) with time

Time	**Group G**	**Group C**	**t-value**	**p-value**
Baseline	92.5 ± 6.33	90.7 ± 7.51	**1.004**	**0.320; NS**
1 minute	93.6 ± 7.75	92.4 ± 8.28	**0.580**	**0.565; NS**
3 minutes	90.3 ± 6.89	83.6 ± 6.84	**3.780**	**<0.001; S**
5 minutes	82.3 ± 8.15	75.9 ± 6.74	**3.315**	**0.002; S**
8 minutes	80.1 ± 6.92	77.9 ± 6.31	**1.287**	**0.203; NS**
11 minutes	80.8 ± 7.39	77.8 ± 5.90	**1.738**	**0.088; NS**
15 minutes	80.4 ± 6.83	78.6 ± 6.12	**1.075**	**0.287; NS**
20 minutes	78.8 ± 6.39	75.6 ± 6.55	**1.915**	**0.061; NS**
25 minutes	77.6 ± 6.62	76.1 ± 6.38	**0.894**	**0.375; NS**
30 minutes	79.6 ± 6.44	76.7 ± 6.77	**1.699**	**0.095; NS**
40 minutes	81.2 ± 7.58	79.6 ± 6.90	**0.855**	**0.396; NS**
50 minutes	81.9 ± 8.00	81.8 ± 7.97	**0.049**	**0.962; NS**
60 minutes	83.8 ± 6.09	84.1 ± 7.14	**0.175**	**0.862; NS**
70 minutes	85.4 ± 6.47	85.43 ±5.99	0.019	0.985; NS
80 minutes	86.9 ± 6.78	87.1 ± 7.10	0.112	0.912; NS
90 minutes	88.42 ± 7.58	88.38 ±7.72	0.020	0.984; NS

Mean arterial pressure was significantly higher in group G compared to group C at 3 minutes and 5 minutes of post spinal anaesthesia induction. In remaining time periods, difference in mean arterial pressure was not significant between two groups. Highest mean arterial pressure (MAP) was recorded in group G at 1 minute and lowest MAP was recorded in group C at 20 minutes

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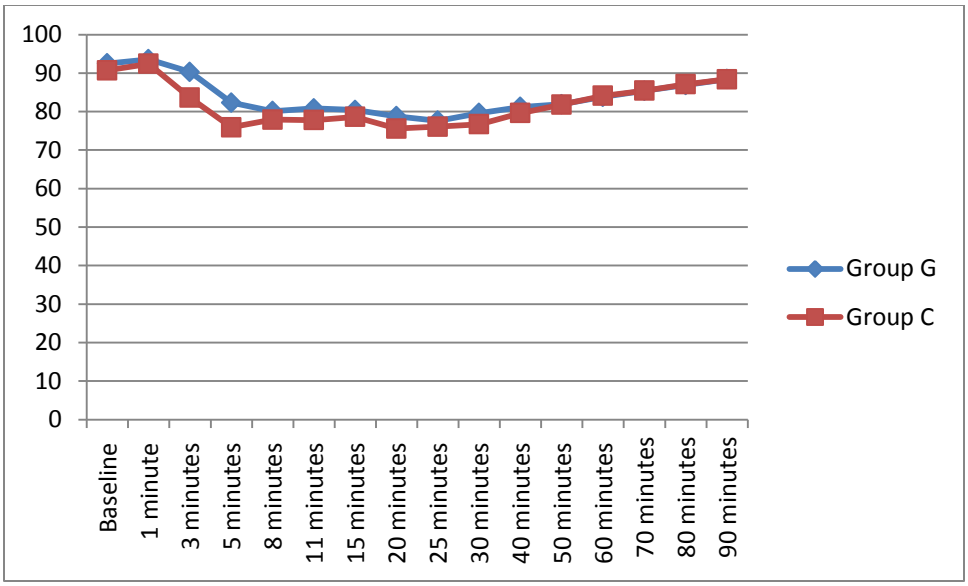

Table no. 6 : **Distribution of the groups by incidence of hypotension**

Incidence of Hypotension	Groups		p-value
	Group G	Group C	
Baseline	0 (0%)	0 (0%)	1.000; NS
1 minute	0 (0%)	0 (0%)	1.000; NS
3 minutes	2 (6.7%)	8 (26.7%)	0.038; S
5 minutes	5 (16.7%)	12 (40%)	0.045; S
8 minutes	7 (23.3%)	10 (33.3%)	0.390; NS
11 minutes	5 (16.7%)	8 (26.7%)	0.347; NS
15 minutes	4 (13.3%)	7 (23.3%)	0.317; NS
20 minutes	2 (6.7%)	8 (26.7%)	0.038; S
25 minutes	2 (6.7%)	6 (20%)	0.255; NS*
30 minutes	1 (3.3%)	8 (26.7%)	0.030; S*
40 minutes	1 (3.3%)	5 (16.7%)	0.197; NS*
50 minutes	0 (0%)	3 (10%)	0.236; NS*
60 minutes	0 (0%)	1 (3.3%)	1.000; NS*
70 minutes	0 (0%)	0 (0%)	1.000; NS
80 minutes	0 (0%)	0 (0%)	1.000; NS
90 minutes	0 (0%)	0 (0%)	1.000; NS

S = Significant; NS = Not significant; * = Yate's p-value

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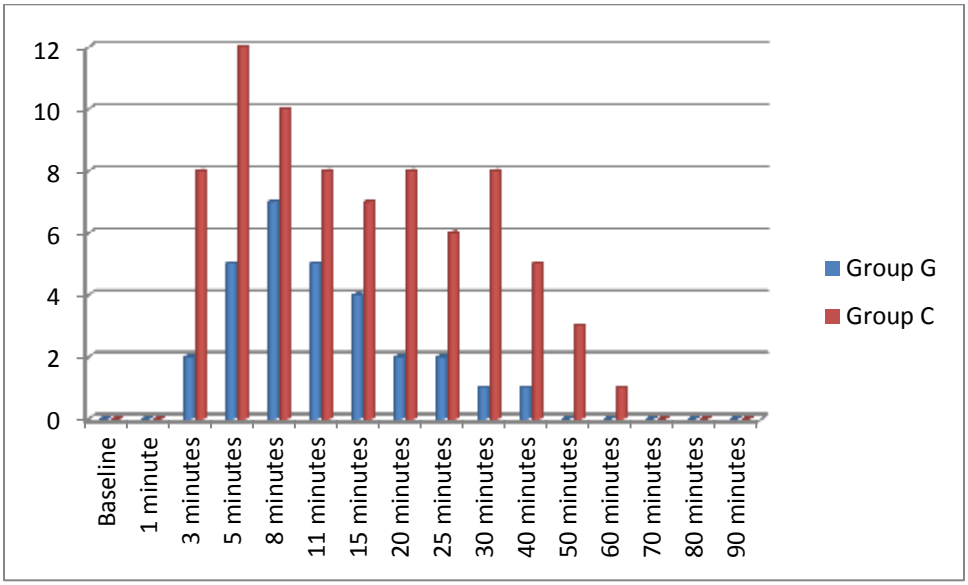
Graph 6: Bar diagram showing the incidence of hypotension in two groups



Mean amount of ephedrine used in group G was 8.4 ± 3.73 milligrams and in group C was 11.4 ± 5.31 milligrams. This was significantly higher in group C compared to group G. ($p<0.05$; Significant)

Atropine was used only once in group C and not used at all in group G. The mean amount of atropine used in group C was 0.02 ± 0.11 milligrams and in group G was 0.00 ± 0.00 milligrams. This difference was not significant statistically. ($p>0.05$; Not significant)

At 3 minutes, 5 minutes, 20 minutes and 30 minutes, significantly higher number of patients in group C was shown hypotension compared to patients in group G. In other time periods, the difference in incidence of hypotension was not significant statistically. At 1minute, 70 minutes and 90 minutes, none of the patients in both groups have shown hypotension.

Table no. 7: **Distribution of the groups by incidence of intra-operative nausea and vomiting, post-operative nausea and vomiting (PONV) and dryness of mouth adverse events**

Adverse events	**Group G**	**Group C**	**p-value**
Intra-operative nausea and vomiting	2 (6.7%)	5 (16.7%)	**0.421; NS***
Post-operative nausea and vomiting (PONV)	1 (3.3%)	4 (13.3%)	**0.350; NS***
Dryness of mouth	10(33.3%)	3 (10%)	**0.028; S**

S = Significant; NS = Not significant; * = Yate's p-value

In group G, adverse events like intra-operative nausea and vomiting occurred in 2 (6.7%) women, post-operative nausea and vomiting occurred in 1 (3.3%) woman and dryness of mouth in 10 (33.3%) women.

In group C, adverse events like intra-operative nausea and vomiting occurred in 5 (16.7%) women, post-operative nausea and vomiting occurred in 4 (13.3%) women and dryness of mouth in 3 (10%) women.

Though the incidence of intra-operative nausea and vomiting, and post-operative nausea and vomiting was higher in group C compared to group G, difference was not significant statistically. ($p>0.05$; Not significant)

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Incidence of dryness of mouth was significantly higher in group G compared to group C. ($p<0.05$; significant

Fig No. 7 **incidence of adverse events in both groups**

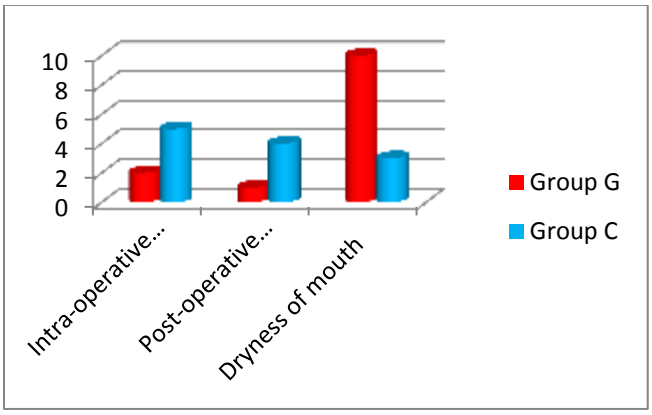
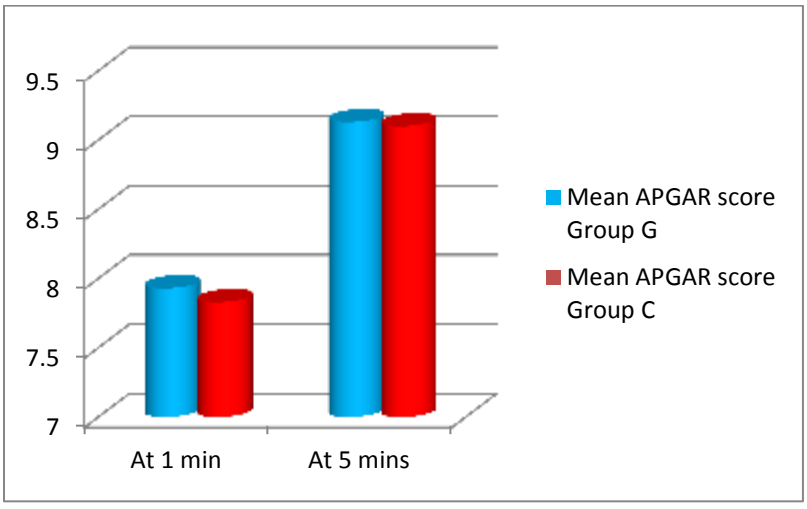


Table no 8: Distribution of the groups by "APGAR scores of the babies"

	Mean APGAR score		**t-value**	**p-value**
	Group G	**Group C**		
At 1 min	7.93 ± 0.25	7.83 ± 0.38	**1.204**	**0.233; NS**
At 5 mins	9.13 ± 0.35	9.1 ± 0.31	**0.351**	**0.727; NS**

Mean APGAR scores at 1 minute were 7.93 ± 0.25 and 7.83 ± 0.38 in group G and group C respectively. Mean APGAR scores at 5 minutes were 9.13 ± 0.35 and 9.1 ± 0.31 in group G and group C respectively. In both time periods, mean APGAR score difference between two groups is does not vary much and is not significant statistically. ($p>0.05$)

Fig No. 8: **Distribution of the groups by "APGAR scores of the babies**



DISSCUSION

The Present study was done in parturients posted for elective caesarean section (LSCS) in Government general hospital, Kurnool, from MARCH 2022 to JULY 2023.

In this study, all parturients in the two groups (n=60) were of similar age, gender, body-weight, height, BMI and surgical duration. There was no statistical difference between the groups

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regarding demographic criteria. The mean height (Ht) of the parturients in group-G was 158.5 cm and 157.1 cm in group-C, hence 2 ml hyperbaric bupivacaine 0.5% was utilized for spinal-anaesthesia in this study.

CONCLUSION

Pre-treatment before administering spinal anaesthesia (SA) in pregnant women who are posted for elective caesarean sections with 0.2 mg of glycopyrrolate in patients decreases the incidence of hypotension[5, 6,7] before the extraction of the neonate. Glycopyrrolate also reduces the incidence of bradycardia. It also decreases the requirement of vasopressor used. It increases the incidence of dryness of mouth. Hence it can be concluded that prophylactic glycopyrrolate for pregnant women who are undergoing elective caesarean section under spinal anaesthesia is advantageous in preventing maternal hypotension, vasopressor use and incidence of maternal bradycardia.

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