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Original Research Paper

Anesthesiology

TAILORMADE NEURAXIAL BLOCK IN DAYCARE PELVIC BRACHYTHERAPY: A REAL CHALLENGE FOR ANAESTHESIOLOGIST

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ABSTRACT

Background: Pelvic brachytherapy requiring spinal anaesthesia has some noteworthy concerns. Ensuring hemodynamic stability in unsupervised conditions post procedure and speedy recovery for early discharge of the patients remains an anaesthetic challenge.

Aim: To find an alternative to conventional intrathecal bupivacaine for faster recovery and early unassisted discharge post brachytherapy.

Material and method: With ethical approval, study was completed with 60 ambulatory patients diagnosed with carcinoma eligible for pelvic brachytherapy were enrolled for spinal anaesthesia. They were randomized by concealed envelope technique and allocated into either Group C(1%choloroprocaine 3ml), Group L(2%lignocaine 0.5ml with 0.5% hyperbaric bupivacaine 1.5ml)or Group B(0.5%hyperbaric bupivacaine 2ml). Intraoperative hemodynamics ,block characteristics was recorded. Full regression of block, time to unassisted ambulation and independent micturition were the primary outcome of study. Incidence of adverse effects was noted. Appropriate statistical tests SPSS. 20 were used for analysis.

Result: Block onset, SBP, MAP were significantly better in Group C compared to B , L. Time to two segment and complete regression, independent ambulation, micturition was significantly less with choloroprocaine followed by lignocaine with hyperbaric bupivacaine.

Conclusion: Intrathecal choloroprocaine demonstrated best patient hemodynamics, and least time to patient discharge followed by bupivacaine in combination with lignocaine compared to bupivacaine alone.

KEYWORDS : Brachytherapy, Choloroprocaine, Bupivacaine, Lignocaine, Daycare, Spinal anaesthesia

INTRODUCTION

Regional anaesthesia is gaining popularity in ambulatory surgeries for excellent operating conditions, improved analgesia, fewer side effects , early ambulation and minimal expense. Brachytherapy is one such surgical procedure where the demand of regional anaesthesia is at rise for both analgesia and immobilizationfor successful placement of implants. The numerouno challenge of brachytherapy session is the transport of anaesthetised patients to multiple locations where hemodynamic monitoring may be unavailable especially in resource constrained setups.

The perioperative management followed byfail safe recovery to allow early discharge of such moribund patients is of prime concern for the attending anaesthesiologist.

For decades,intrathecal 5 % hyperbaric lignocaine was used as the ideal short acting anaesthetic agent but its reputation has been maligned with reports of transient neurologic symptoms and cauda equina syndrome when used in large doses.Popularly used intrathecal 0.5 % hyperbaric bupivacaine provides impeccable anaesthesia. However its profound sympathetic blockade and prolonged duration of action demands vigilant monitoring.

Previous studies have found that the addition of small dose lignocaine to bupivacaine shortens the duration of action without causing neurotoxicityor compromising the block quality. On the other hand the use of intrathecal Chloroprocaine for its rapid onset, faster offset , reliable efficacy could be an alternative in short procedures.

In our study we have compared 1%choloroprocaine, combination of 2%lignocaine with 5%hyperbaric bupivacaine[1] and low dose 0.5%hyperbaric bupivacaine for spinal anaesthesia in patients undergoing pelvic brachytherapy where the duration is hardly of an hour.Our intention was to find an alternative to conventional bupivacaine to allow quicker recovery and early unassisted discharge on an outpatient basis.

MATERIAL AND METHOD

After obtaining Ethics Committee approval the study was conducted in the brachytherapy room and oncology wards of Medical College Kolkata within the study period of 10 months. Patients were enrolled from outdoor PAC.

Sample size

We calculated the sample size using the formula from previous studies

$$n=(2(Z\alpha+Z_{(1-\beta)})^{2\sigma 2})/\Delta^2$$

Keeping the power of study at 80% and alpha error at 5%,we found the minimum sample had to be 13,18 respectively. With consideration of 5-10% dropout , we needed 60 patients with 20 in each arm.[2]

Sixty ambulatory patients of ASA grade II or III of either sex of 18years and above,diagnosed with urological, gynaec ological,or rectal carcinoma requiring pelvic brachytherapy, were enrolled into the study into either of three groups. Patients with known neurological disorder, lower back pain, previous spinal surgery or deformity ,low platelet count or coagulation disorder, local site infection, allergy to local anaesthetics were excluded.

The eligible patients were enrolled after proper explanation and obtaining informed written consent. On the day of surgery, they were randomly allocated into respective groups by computer generated numbers available in sealed envelopes. The three groups were Group C – receiving 1% choloroprocaine 30mg , Group L- receiving 0.5ml 2% preservative free lignocaine with 1.5ml 0.5%hyperbaric bupivacaine and Group B- receiving 2ml 0.5%hyperbaric bupivacaine.

The patients participating were priorly advised during the PAC about fasting for at least six hours after last solid meal and were instructed before hand to have Pantoprazole 40mg orally in the early morning on the day of procedure. On the day of procedure, a suitable peripheral line was done with 18 or 20 gauge cannula and were preloaded with 10 ml/ kg of Ringer's lactate solution over 20 minutes. Standard monitors like E.C.G., non invasive blood pressure and pulse oxymeter probe were attached to the patient and baseline reading were recorded.

Spinal anaesthesia was performed under sterile condition after local infiltration of skin with 1%lignocaine.With the patient in the sitting position, the subarachnoid space was entered at the L3-4/L2-3interspace via the midline approach using a 25G quincke spinal needle. After confirming free flow of CSF , the spinal drug according to the allocated group was injected over 15-20 seconds. The needle was removed and the puncture site was covered with a sterile dressing. The patient was turned supine in horizontal plane. This part of the procedure was conducted by one anaesthesiologist who was aware about the patient's group.Another non participating anaesthetist, blinded to the treatment group of the patient, was responsible for patient monitoring and clinical data collection for the study.

The level of sensory block was assessed in a caudal to cephalad direction using the loss of cold sensation to ice,and the C5-C6 dermatome was used as an unblocked reference point at 1minute interval for first 15 minute then 3 minute interval for next 15 minutes, then 10 minute interval for the remaining period. During testing of sensory block level when four consecutive testing detected the same level of sensory block, that level of sensory block was considered as peak sensory block level.The minimum time taken to reach the peak sensory block was considered as onset time. For assessment purpose all the time factor were counted after completion of spinal injection. Sensory block height at least T_{10} or more was considered as adequate anaesthesia for the procedure. At the peak sensory block patient was allowed for procedure. After starting of procedure patient was assessed for quality of sensory block. Depending upon the degree of sensation the patient felt during surgery, quality of sensory block was and categorized as

LEVEL	QUALITY
A	Complete absence of sensation
B	Sensation of motion only
C	Mild discomfort but no analgesic required
D	Pain requiring analgesia

Patients with sensory blockade quality of category D were considered as failed block and excluded from study and managed with intravenous analgesia or general anaesthesia. Motor block was assessed by modified Bromage scale.

GRADE	CRITERIA	DEGREE OF BLOCK
0	No Motor block	Nil
1	Inability to raise extended leg; able to move knees and feet	Partial(33%)
2	Inability to raise extended leg and move knee; able to move feet	Almost complete (66%)
3	Complete block of motor limb	Complete (100%)

During procedure, evaluation of the motor block was suspended until the end of the procedure. Peak sensory block and time taken to reach it was assessed and noted. Time taken for two segment regression and at S2 segment regression were noted. During procedure SBP,DBP, MAP, Heart Rate and pulse oximetry were recorded at 5 minute, 10 minute, 20 minute, 30 minute, and 45 minute.

Any episode of hypotension , bradycardia and desaturation was noted. A reduction of MAP more than 20% reduction of baseline MAP was defined as hypotension. Bradycardia was defined as any episode of heart rate less than 40 per minute with or without symptoms. Oxygen desaturation was defined as reduction of SpO_2 by 94% or less than that in room air. Episode of hypotension was treated with 100 ml RL in bolus infusion followed by phenylephrine bolus(50 microgram) if required. Bradycardia and desaturation was treated with injection atropine and moist oxygen 4-5 liters through Hudson face mask, respectively.

After completion of surgery patient was transferred to the recovery room for observation.

The primary outcome variable included the time taken to following clinical criteria for discharge from the hospital, i.e.

- *S2 segment regression of sensory block.*
- *Ability to walk unaided.*
- *Ability to void urine.*

Secondary outcomes included the following comparisons:

- *Time to eligibility for discharge from theatre recovery area:* two segment regression from peak sensory height with hemodynamic stability.
- *Quality of analgesia*
- *Degree of motor blockade:* Measured at the time of peak sensory level and at two segment regression
- *Side-effects:* Nausea and/or vomiting, pain in non operative sites(if any)
- *Need for hospital stay*
- *Total dose Phenylepinephrine if required.*

Since brachytherapy takes hardly 30-45minutes,and not very extensive,there is no requirement of post operative rescue analgesics. However if any patient demanded for analgesics, Paracetamol 1gm infusionwas given .At the next outdoor visit, patients were specifically asked if they had any pain unrelated to the operative site, specifically in the buttocks, thighs or lower limbs(transient neurological symptoms) or urinary incontinence. Patients were encouragedcto immediately consult the radiotherapist or the anaesthetist in the interim period if any symptoms appeared.

RESULT AND ANALYSIS

Fig 1: Consort Diagram

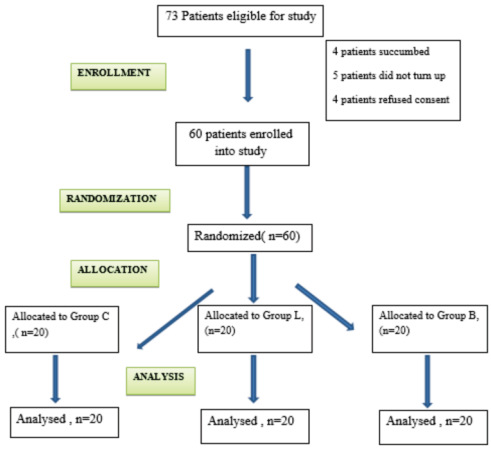


Table no. – 1. Distribution of study subjects according to Demographic parameters , Gender, ASA

Groups	Age(years)#	Body weight(KG)#	Height(cm)#	Gender$ (M/F)	ASA$ (II/III)
Group-B(n=20)	59.30 ± 13.047	53.05 ± 5.624	156.55 ± 4.893	6/14	8/12
Group-C(n=20)	59.90± 10.789	48.05 ± 5.995	159.95 ± 6.151	4/16	9/11

Group-L(n=20)	59.70± 10.152	49.10 ± 6.103	156.30 ± 3.854	8/12	8/12
Significance	P=0.059	P=0.062	P= 0.055	P=0.065	P=0.937
#Data expressed as mean ± S.D Test used : One way ANOVA $Data expressed in numbers Test used : One way ANOVA P<0.05 is significant					

Table no. – 1shows Demographic parameters were compara ble between the three groups

Table No 2: Primary Outcome Variables.

	Group C(n=20)	Group L(n=20)	Group B(n=20)	Significance
Time of two segment regression(min)*	32.25 ± 3.45	44.1 ± 6.76	67.5 ± 11.95	P<0.05
Time of S_2 segment regression(min)*	101.1 ± 18.22	155.75 ± 25.15	195.5 ± 13.37	P<0.05
Time to ambulation(min)*	107.7 ± 18.46	162.85 ± 24.42	240.0 ± 21.34	P<0.05
Time to void(min)*	115.1 ± 18.83	170.5 ± 24.38	287.5 ± 37.22	P<0.05
Need for hospital stay#	0/20	1/20	3/20	P=0.0586
# data expressed as numbers Test used:Chi Square test *data expressed as mean ±S.D Test used: One way ANOVA P<0.05 is significant				

Table No 2: Primary Outcome Variables.

Time of two segment regression,Time of S_2 segment regression,Time to ambulation ,Time to voidwas earlier in Group C (Chloroprocaine) compared to Group L(Lignocaine + Bupivacaine) compared to Group B(Hyperbaric Bupivacaine) was statistically significant.(P<0.05)

Need for hospital stay was lowest in Group C (Chloro procaine) 0/20 compared to Group L(Lignocaine + Bupivacaine) 1/20compared to Group B(Hyperbaric Bupivacaine)3/20

Table 3:Time of onset of block, time to reach peak sensory and motor time between the Groups.

	Group-B (n=20)	Group-C (n=20)	Group-L (n=20)	significance
Time of Onset (min)	5.25 ± 1.446	2.55 ± 0.604	6.70 ± 1.455	**P < 0.001**
Peak Time Sensory (min)	8.70 ± 2.130	5.35 ± 1.089	8.55 ± 1.572	**P < 0.001**
Peak time motor (Min)	17.50 ± 3.749	12.00 ± 2.616	14.60 ± 2.563	**P < 0.001**

Table 3 shows that the time of onset of block, time to reach peak sensory and motor time was found to be significantly (P<0.0001) least in Group C, followed by Group L and longest to be in Group B

Table 4 .Baseline variables between the Groups

Groups	SBP	DBP	MAP	HR	SPO2
Group-B	123.9 ± 11.373	82.45 ± 13.355	85.85 ± 9.853	82.45 ±18.707	99.6 ± 0.821
Group-C	125.8 ± 16.666	74.95 ± 10.660	87.55 ± 12.866	77.30 ±9.804	99.8 ± 0.410
Group-L	127.8 ± 10.304	80.45 ± 8.556	93.15 ± 8.506	74.80 ± 8.186	99.75 ± 0.550
Significance	P = 0.643	P = 0.093	P = 0.082	P = 0.178	P = 0.570

One way ANOVA

Table 4 . Baseline variables were comparable between the Groups

Table 5: At 5 Min The SBP, DBP, MAP, HR &SPO2 between the Groups.

Groups	SBP	DBP	MAP	HR	SPO2
Group-B	116.0 ± 13.243	71.6 ± 11.427	81.2 ± 12.38	79.45 ±20.156	99.6 ± 1.094
Group-C	123.5 ± 14.446	75.0 ± 11.197	87.65 ± 12.775	77.55 ±8.858	100.0 ± 0.000
Group-L	125.9 ± 9.821	78.8 ± 8.813	91.80 ± 7.991	74.60 ± 7.701	99.7 ± 0.801
Significance	**P = 0.044**	P = 0.109	**P = 0.015**	P = 0.521	P = 0.252

One way ANOVA

Table 5: At 5 Min The SBP, DBP, MAP HR & SPO2 between the Groups show that the change SBP variation or decrease is maximum in Group B ie. Hyperbaric Bupivacaine(116.0 ± 13.243) followed by group Group C ie.chloroprocaine (123.5 ± 14.446) and least in Group L(125.9 ± 9.821), which is statistically significant. (P = 0.044)Similarly the change in MAP also follows the same pattern,ie.decrease is maximum in Group B ie. Hyperbaric Bupivacaine(81.2 ± 12.38) followed by group Group C ie.chloroprocaine (87.65 ± 12.775) and least in Group L(91.80 ± 7.991)which is also statistically significant. The HR and The DBP also follow the similar trend but are not statistically significant.

SpO2 remains unaltered for all groups.

Table6. AT 10 Min The SBP, DBP, MAP HR &SPO2 between the Groups.

Groups	SBP	DBP	MAP	HR	SPO2
Group-B	115.3 ± 11.351	70.55 ± 9.451	116.65 ± 16.092	80.0 ±17.595	99.7 ± 0.801
Group-C	123.15 ± 13.674	74.3 ± 11.001	85.8 ± 12.107	77.45 ±9.029	100.0 ± 0.000
Group-L	126.15 ± 10.594	78.85 ± 8.732	91.95 ± 8.519	74.75 ± 9.909	99.8 ± 0.523
Significance	**P = 0.017**	**P = 0.033**	P = 0.546	P = 0.435	P = 0.226

One way ANOVA

Table 6 AT 10 MIN The SBP, DBP, MAP HR & SPO2 between the Groups show that the change SBP variation or decrease is maximum in Group B ie. Hyperbaric Bupivacaine(115.3 ± 11.351) followed by group Group C ie.chloroprocaine (123.15 ± 13.674) and least in Group L(126.15 ± 10.5), which is statistically significant.(P = 0.01). similarly the fall in DBP was also follows the same pattern,ie. decrease is maximum in Group B ie. Hyperbaric Bupivacaine(70.55 ± 9.4) followed by group Group C ie.chloroprocaine (74.3 ± 11.0) and least in Group L(78.85 ± 8.7) which is also statistically significant.(P = 0.033).

SpO2 remains unaltered for all groups.

Groups	SBP	DBP	MAP	HR	SPO2
Group-B	115.65 ± 11.254	70.35 ± 9.767	80.35 ± 10.251	76.4 ±14.284	99.7 ± 0.801
Group-C	123.05 ± 15.039	73.55 ± 11.455	86.85 ± 13.319	76.15 ±9.051	99.7 ± 0.801
Group-L	124.25 ± 10.119	77.3 ± 8.304	89.95 ± 7.789	74.0 ± 9.503	99.75 ± 0.716
Significance	P = 0.066	P = 0.095	**P = 0.020**	P = 0.759	P = 0.973

One way ANOVA

Table 7: AT 20MIN The SBP, DBP, MAP HR & SPO2 between the Groups shows that MAP variation was maximum in Group B ie. Hyperbaric Bupivacaine(80.35 ± 10.2) followed by group Group C ie.chloroprocaine (86.85 ± 13.3) and least in Group L(89.95 ± 7.78), which is statistically significant.**(P = 0.02)**, the SBP and the DBP also follow the similar trend though notstatistically significant.

SpO2 remains unaltered for all groups.

Table 8:AT 30 MINThe SBP, DBP, MAP ,HR &SPO2 between the Groups.

Groups	SBP	DBP	MAP	HR	SPO2
Group-B	117.95 ± 12.808	72.05 ± 8.262	81.3 ± 10.084	76.0 ±14.301	99.7 ± 0.801
Group-C	122.9 ± 14.977	73.35 ± 12.248	86.95 ± 13.896	76.45 ±9.162	99.8 ± 0.523
Group-L	122.75 ± 8.926	77.6 ± 6.628	89.4 ± 7.044	74.0 ± 8.950	99.7 ± 0.801
Significance	P = 0.368	P = 0.155	P = 0.057	P = 0.759	P = 0.880

One way ANOVA

Table 8:AT 30 MIN The SBP, DBP, MAP HR & SPO2 between the Groups show that the MAP and DBP variation was maximum in Group B ie. Hyperbaric Bupivacainefollowed by Group C ie.chloroprocaineand least in Group L though not statistically significant.

SpO2 remains unaltered for all groups.

Table 9:AT 45 MINThe SBP, DBP, MAP HR &SPO2 between the Groups.

Groups	SBP	DBP	MAP	HR	SPO2
Group-B	118.3 ± 11.280	72.2 ± 8.483	82.35 ± 9.449	74.4 ±15.132	100.0 ± 0.000
Group-C	122.45 ± 15.323	73.3 ± 11.827	86.3 ± 12.153	76.65 ±8.261	100.0 ± 0.000
Group-L	123.8 ± 9.002	77.35 ± 7.436	89.45 ± 6.878	74.00 ± 8.596	99.85 ± 0.489
Significance	P = 0.334	P = 0.199	P = 0.078	P = 0.720	P = 0.162

One way ANOVA

Table 9:AT 45 MIN The SBP, DBP, MAP HR & SPO2 between the Groups show that show that the MAP and DBP variation was maximum in Group B ie. Hyperbaric Bupivacaine followed by Group C ie.chloroprocaineand least in Group L though not statistically significant.

SpO2 remains unaltered for all groups.

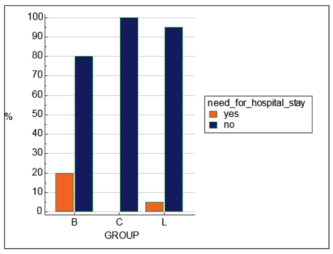
Table 10: Quality of Block between the Groups

	GROUP				
Quality_of_block	GROUP B	GROUP C	GROUP L	TOTAL	
1	10	16	14	40 (66.7%)	X^2=4.2 DF=2 P = 0.1225
2	10	4	6	20 (33.3%)	
TOTAL	20 (33.3%)	20 (33.3%)	20 (33.3%)	60	

CHI SQUARE TEST

Table 10: Quality of Block between the Groups shows that Group C>>GroupL>>GroupB significantly.

Graph1: Need for Hospital stay between the groups



Graph1: Need for Hospital stay between the groups shows that the 20%patients in Group B and 5% in Group L while none in Group C needed hospital stay.

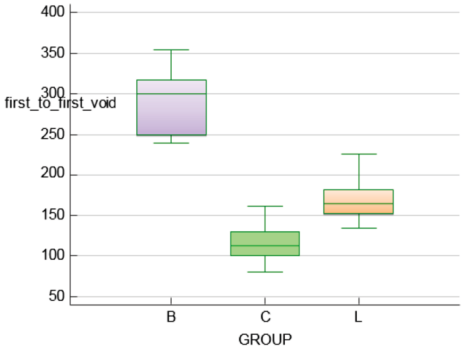
Table 11: PONV between the Groups

	GROUP				
PONV	B	C	L	TOTAL	
1	4	0	4	8 (13.3%)	Chi-squared =4.615 DF=2 P = 0.0995
2	16	20	16	52 (86.7%)	
TOTAL	20 (33.3%)	20 (33.3%)	20 (33.3%)	60	

CHI SQUARE TEST

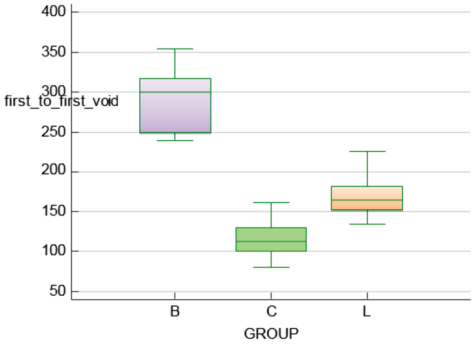
Table 11: PONV between the Groups shows that GroupC had no incidence of PONV, Group B and Group L had 4 patients each.

Graph2:PONV between the Groups



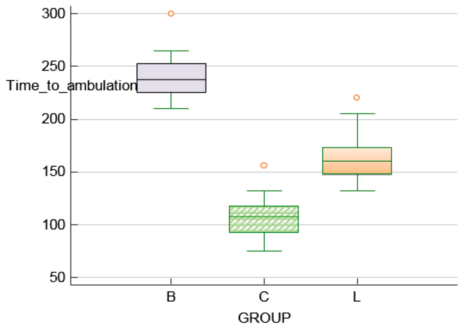
Graph2: PONV between the Groups shows that20% of GroupB and 20% of Group L had PONV but 0 patients in Group had PONV.

Graph 3:First to void urine between the Groups



Graph 3:shows that Group C(115.1 ± 18.8) were the 1st to void urine compared to Group L(170.5 ± 24)compared to Group B (287.5 ± 37)

Graph4: Time to ambulation between the Groups



Graph4: Time to ambulation between the Groups shows that patients in GroupC were the earliest to ambulate compared to those in GroupL than to Group B.

DISCUSSION

Pelvic brachytherapy,a daycare procedure, primary needs analgesia and minimal relaxation intraoperatively for placement of implants. The challenge lies in management of patients already critical with associated comorbidities , their hemodynamic stability during unsupervised transport to multiple centres. Thus ensuring both hemodynamic stabilityand assuring a speedy recovery to allow early discharge carries utmost importance for an anaesthesiologist. Conventional hyperbaric bupivacaine for spinal anaesthesia provides excellent analgesia but its long duration of blockade makes it questionable for daycare.Addition of small dose of lignocaine is known to produce spinal block with similar property of bupivacaine except neurotoxicity but with faster regression. Choloroprocaine is ultra short acting local anaesthetic is an interesting alternative to both lignocaine and bupivacaine with faster regression of block effects with similar onset.

In our study, our principle finding was that 1% 30mgCholorop rocaine was the best spinal local anaesthetic offering desirable analgesia and stable hemodynamics. Owing to its rapid regression, the patients ambulated and voided earlier resulting in fast tracking of surgery.Interestingly, if choloroprocaine is unavailable ,our next best alternative can be combination of small dose of preservative free lignocaine to bupivacaine for similar outcome like choloroprocaine.

Though the reason of accelerated recovery is postulated as the addition of lidocaine might have induced vasodilation of spinal bloodvessels, thus enhancing the clearance of bupivacaine from the intrathecal space. This is in agreement with the results of Clement et al and Sara El-Adawy[1,3]

- Demographic parameters were comparable.
- Time of onset of block, time to reach peak sensory and motor time was found to be significantly ($P<0.0001$) least in Group C, followed by Group L and longest to be in Group B
- Baseline hemodynamic parameters were comparable between the three groups. However at 5, 10,20min the SBP,DBP,MAP were significantly less in Group B. But none of the patients needed management by Phenylepine phrine.100ml fluid i.v fluid bolus had sufficed. The results corroborate study of Nair et al.[4]
- Our primary outcome variables(time to S2 segment regression block, time to ambulation and independent micturition) were significantly found minimum in Group C followed by Group L.

Similarly, Yoos et al. compared 2-Chloroprocaine with bupivacaine and demonstrated a 1.7 times faster regression of the sensory block with 2-Chloroprocaine .[5]

Sung-Jin Lee et al had also found similar effect for S2 regression with addition of small dose lignocaine but for two segment regression it was higher with bupivacaine alone. Lignocaine induced vasodilatation causing rapid clearance of drug.[6]

The mean difference between time to ambulate was 133min (Group C vs Group B) and 73 min (Group L vs Group B) respectively. This difference is more in comparison to our reference studies. An important reason for this significant difference is contributed by the patient profile and procedure itself.[7]

The quality of analgesia was satisfactory in all the three groups.

Four out of twenty patients experienced PONV in group L and B. With a small dose of spinal anaesthetic drug and insignificant hypotension, it is unlikely to be precipitated by spinal anaesthesia alone. The brachytherapy itself and the co-existent condition of these patients are also responsible for many of the adverse events especially PONV as also noted by KC Shekhar and Vijaylakshmi Chandrashekhar.[8]

There was no report of TNS in subsequent visits.

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