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**1**

**EDITORIAL**

**YOGA AND BASIC MEDICAL SCIENCES**

**FIRST YEAR OF INTERNATIONAL DAY OF YOGA 21 June 2015**

**Dr janardan Bhatt**

With effort of Honorable Prime Minister of India Shri Narendra Modi, United Nations General Assembly (UNGA) declared and celebrated on 21 June as INTERNATIONAL DAY OF YOGA for purpose of spread of knowledge and application use of YOGA for health, harmony and inter peace. Though in a particular case that one may require diagnosis or medical attention, consult health experts before practicing Yoga. Yoga is an invaluable gift of ancient Indian tradition. It embodies unity of mind and body; thought and action; restraint and fulfillment; harmony between man and nature and a holistic approach to health and well-being. Yoga is not about exercise but to discover the sense of oneness with ourselves,

the world and Nature. By changing our lifestyle and creating consciousness, it can help us to deal with climate change. Let us work towards adopting an International Yoga Day."

WHO has already mentioned the value of spiritual well being health in definition of health and YOGA practice gives true answer to spiritual dimension of health

Yoga is essentially a spiritual discipline based on an extremely subtle Science which focuses on bringing harmony between mind and body. It is an art and science for healthy living. The word "Yoga" is derived from the Sanskrit root *yuj* meaning "to join", "to yoke" or "to unite".

According to Yogic scriptures, the practice of Yoga leads to the union of individual consciousness with universal consciousness. According to modern scientists, everything in the universe is just a manifestation of the same quantum firmament. One who experiences this oneness of existence is said to be "in Yoga" and is termed as a yogi who has attained a state of freedom, referred to as *mukti*, *nirvāna*, *kaivalya* or *moksha*. "Yoga" also refers to an inner science comprising of a variety of methods through which human beings can achieve union between the body and mind to attain self-realisation. The aim of Yoga practice (*sādhana*) is to overcome all kinds of sufferings that lead to a sense of freedom in every walk of life with holistic health, happiness and harmony. Brief history and development of Yoga

The history of yoga is in many millenniums but sage Maharishi Patanjali systematized and codified the existing Yogic practices, its meaning and its related knowledge through Patanjali's Yoga Sutras.

After Patanjali, many sages and Yoga masters contributed greatly for the preservation and development of the field through well documented practices and literature. Yoga has spread all over the World by the teachings of eminent Yoga masters. Traditional schools of Yoga. The different philosophies, traditions, lineages and guru-shishya paramparas of Yoga led to the emergence of different traditional schools. These include gnāna Yoga, Bhakti Yoga, Karma Yoga, Pātanjala Yoga, Kuṇḍ ā lini Yoga, Haṭha Yoga, Dhyāna Yoga, Mantra Yoga, Laya Yoga, Rāja Yoga, Jain Yoga, Bouddha Yoga etc. Each school has its own approach and practices that lead to the ultimate aim and objectives of Yoga. Yogic practices for health and wellness

The widely practiced Patanjali Yoga sadhanas have eight steps they are: Yama, Niyama, Āsana, Prānāyāma, Pratyāhara, Dhāraṇa, Dhyāna, Samādhi.

A few dietary guidelines can ensure that the body and mind are flexible and well-prepared for practice. A vegetarian diet is usually recommended, and for a person over 30 years, two meals a day should suffice, except in cases of illness or very high physical activity or labour.

Though Yoga is essentially a path to liberation from all bondage., medical research in recent years has uncovered many physical and mental benefits that Yoga offers, corroborating the experiences of millions of practitioners. A small sampling of research shows that: Yoga is beneficial for physical fitness, musculoskeletal Functioning and cardio-vascular health. It is beneficial in the management of diabetes, respiratory

disorders, hypertension, hypotension and many life style related disorders. Yoga helps to reduce depression, fatigue, anxiety disorders and stress. Yoga regulates menopausal symptoms. In essence, Yoga is a process of creating a body and mind that are stepping-stones, not hurdles, to an exuberant and fulfilling life. Now we people basic medical sciences had responsibility to prove real benefits by doing basic and applied researches give prove more insight in evidence based medicine.

**Reference** with thanks: from INTERNATIONAL DAY OF YOGA **booklet on Common Yoga Protocol**

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2]

## **PREVALENCE OF LEARNING STYLE PREFERENCES AMONGST FIRST YEAR MEDICAL STUDENTS.**

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### **Abstract :**

**Introduction:** First year medical students have to incorporate vast amount of information. Learning is influenced by the mode of the input that has been presented to the students. Visual ,auditory ,reading/writing and kinesthetic are amongst the known modes of information presentation.

**Objective:** The present study was aimed at trying to understand the different learning preferences that medical students prefer to have and thereby, try and incorporate those learning preferences into teaching methods.

**Method:** The present study was conducted on 120 first year medical students in the dept of physiology at grant govt. medical college Mumbai. Standard 16 question based VARK questionnaire was administered to the students and assessed to decipher their learning styles.

**Results:** Analysis of the study revealed that only 34.17% preferred a single mode or uni-modal way of information presentation and 65.83% preferred multimodal learning methods. Out of the uni-modal learners, preference wise, 4.87% were visual,21.95% were auditory,12.19% were read/write and 60.97% were kinesthetic learners. Amongst the multimodal ones preference wise distribution was 26.58% for two modes(bi-modal),20.25% for three modes(tri-modal), and 53.16 % for all four modes(quad-modal).

Conclusion: knowing about learning preferences can thus enable the instructor to address this diversity of learning styles amongst students and develop appropriate learning approaches.

Keywords: Visual , Auditory, Read/Write, Kinesthetic , uni-modal ,bi-modal, tri-modal, quad-modal, multi-modal, learning styles ,learning preferences.

### **Introduction**

Medical students undergo a drastic change in content as well as matter, in terms of syllabus, when they enter the professional medical colleges. These students in general vary widely in terms of culture ethnicity medium of instruction and level of preparedness but have the same matter to study once they are into the professional course. Owing to their diverse backgrounds and thereby possible different learning styles and preferences, it is indeed a challenge for the teaching faculty to meet the educational needs of all students. Meeting this challenge becomes an onus on the teaching faculty to address this diversity of learning styles amongst students and develop appropriate learning approaches.(1)

A learning style or preference is the complex manner in which , and conditions under which, learners most efficiently and most effectively perceive ,process, store and recall what they are attempting to learn.(2)

We in this study are using Vark as an acronym that stands for four major sensory modes of learning : Visual, Auditory, Read /Write and Kinesthetic depending upon the mode by which a learner prefers to receive information. Amongst the four modes one or more modes are often dominant and preferred by the learners. The present study sheds light on the chosen modes of learning that the medical students tend to adopt during their first year of medical career.

Coming on to the different modes of learning, visual learners learn through seeing drawings, pictures and other image rich teaching tools. Auditory learners learn by listening to lectures , exploring material through discussions, and talking through ideas. Reading /Writing learners learn through interaction with textual materials, whereas kinesthetic learners learn through touching and experiences, that emphasize doing, physical involvement and manipulation of objects.(3)

Our interest to know about preferred learning modes led us to use the Vark inventory tool for assessing individual preferences. The Vark questionnaire developed by ND Fleming was used as the required tool to meet our needs.(4)

### **Materials and methods.**

The Vark questionnaire has been developed by Fleming which identifies the preferences of students for particular modes of information presentation.(4) This questionnaire can be administered both as a hard copy as well as a freeware that can be completed online. We preferred to use the hard copy version on our first year medical students for ease of use and administration. The study was conducted on 120 first year medical students in the department of physiology at Grant Govt. Medical

College and J.J. group of hospitals, Mumbai , after obtaining proper approval from the institutional ethical committee. Even an e-mail confirmation and consent to use this questionnaire for the study was taken from N.D. Fleming, the developer of the VARK questionnaire. Only those students who were interested and volunteered for the present study were taken into consideration after taking their written consent. Students also had the option open, of not participating for the study, if they so wished.

### **Analysis**

The number of students who preferred each mode of learning was divided by the total number of responses to determine the percentage of students in each category. These percentages were then plotted on pi charts to have a clear and vivid imagery about the distribution of different modal preferences amongst the students.(3 for pi charts)

### **Results**

Figure 1 shows the percentage of students who preferred different modes of information presentation. They are as follows: visual (1.67%) auditory (7.5%) reading/writing (4.16%), kinesthetic (20.83%) and multiple modes (65.83%). 34.17 % thus preferred a single mode of information presentation (i.e visual,auditory reading/writing or kinesthetic.)

Figure 2 now shows the further division of the 79 students (65.83% of all students )who preferred multiple modes of information presentation. Of these 79 students some students preferred two modes (bimodal 26.58%),some preferred three modes (trimodal 20.25% ) and some preferred four modes (quad modal 53.16 %). Thus quad modal preferences were seen to occupy more than half of the preferences of multi modal ones. Figure 3 now goes on to show the percentage wise breakup of trimodal and bimodal preferences. Of the students who preferred three modes of information presentation, some students preferred auditory read/write and kinesthetic (ARK 11.39%) , some preferred visual, auditory and kinesthetic(VAK 7.59 %) and some preferred visual ,read/write and kinesthetic (VRK 1.26%).None of the students preferred visual,auditory and read/write combination (VAR 0%).

Of the students who preferred two modes of information presentation, some students preferred auditory and read/write (AR 2.53%) , some preferred visual and auditory (VA 2.53 %) and some preferred read/write and kinesthetic (RK 6.32%),some preferred visual and kinesthetic (VK 5.06%),some preferred auditory and kinesthetic (AK 10.13 %).None of the students preferred visual and read/write combination (VR 0%).

### **Discussion**

Our study involved the first year medical students who had just stepped into a complete different environment after years of school study. The syllabus in the schooling days and that in the professional medical career nowhere match each other in terms of matter, content , vastness and ease of understandability. It is a daunting task for both the medical student as well as the teacher to channelize this vast matter , material and



knowledge into its requisite place. I.e. the memory and understanding of the ardent student.

In this attempt we designed our present study to be conducted on these new comers of professional medical college. The standard 16-item, self reported multiple choice VARK questionnaire designed by Fleming was used for this purpose of evaluating the students preferred modes of information presentation.(4) Out of the 120 students included in the present study 41 (34.17%) preferred a single mode of information presentation whereas 79 students (65.83%) turned out to prefer multiple modes of the students. Of the students who preferred a single mode of information presentation only 7.5% preferred auditory mode of learning which comprised, hearing to instructions, lectures and audio-aids. 4.16 % were those who preferred gathering information just by reading/writing. Probably targets those people who are fervent “BOOK-WORMS” or those who solely rely on notes been dictated by their teachers. Visual mode was preferred by just 1.67 % of students. Most likely, they are those, who prefer information to be presented in the form of visual cues like graphs, charts and flow diagrams. Spatial arrangements and working with symbols seem to be their niche. 20.83 % of the students preferred learning using a mix combination of multiple sensory modes like touch,hearing,sight etc. They would like their learning to be by multisensory inputs like real life situations, workshops, tasks, hands on experiences and role playing.(3,5)

Quite a sizeable proportion of students i.e. 65.83% preferred the multimodal mode of information presentation. These students preferred their information to arrive in a variety of modes, thus balancing their preferences(3), by not clinging on to any specific sensory mode of input. They are often gifted by their innate ability to adapt to different teaching styles encountered during their course of study. They find it easy to opt in and out of different teaching strategies like being more visual in one system and being auditory in the other. Changing input tracts ‘as and when’ required and aligning themselves according to the information modes provided by the instructor seem to be their forte. Thus instructors would seem to provide more benefit by switching on to active learning strategies rather than sticking on to the traditional lecture format, which assumes that all students are auditory learners. Just by introducing active learning strategies and motivating teachers to move from their preferred modes to other learning modes the instructor could easily reach more students because of the better match between teacher and learner styles.(6-17)

Some students prefer one of the modalities over the other three so much that they find it difficult to understand the subject matter unless special care is taken to present it in their own preference mode. To make it so happen ,teaching should be multisensory and filled with variety. Visual learners can thus be targeted by the presence of models and demonstrations. Auditory learners can be reached through discussion during peer instruction(18-19),collaborative testing(20,21) debate (22), games (23-28) and answering questions(9). Manipulating models (30,31) and role playing(32) satisfies

kinesthetic and tactile learners..Cooperative learning exercises, role playing, simulations, models, debates and games are amongst active learning strategies that can be used rampantly and efficiently in large classrooms. All these promote appreciable levels of motivation and involve enthusiasm.

### **Conclusion and summary**

We thus conducted the present study with a motive to check out the prevalence of different learning modes and styles in the students who have managed to make it up to the medical career. Also in the backdrop, keeping in mind the scope of future research, wherein we could possibly see the effect of gender or probably their pre medical schooling and medium of instruction, we keep this study as a building block and foundation, meriting further innovations and research in the future.

Taking into consideration the present study, where we didn't delve into the nuance of doing anything apart from getting a random pool of students and analyzing their learning modes and choices ,we could reason up the proposition that, active learning strategies may be superior to the traditional lecture format in promoting thinking, reasoning, problem solving and decision making skills.

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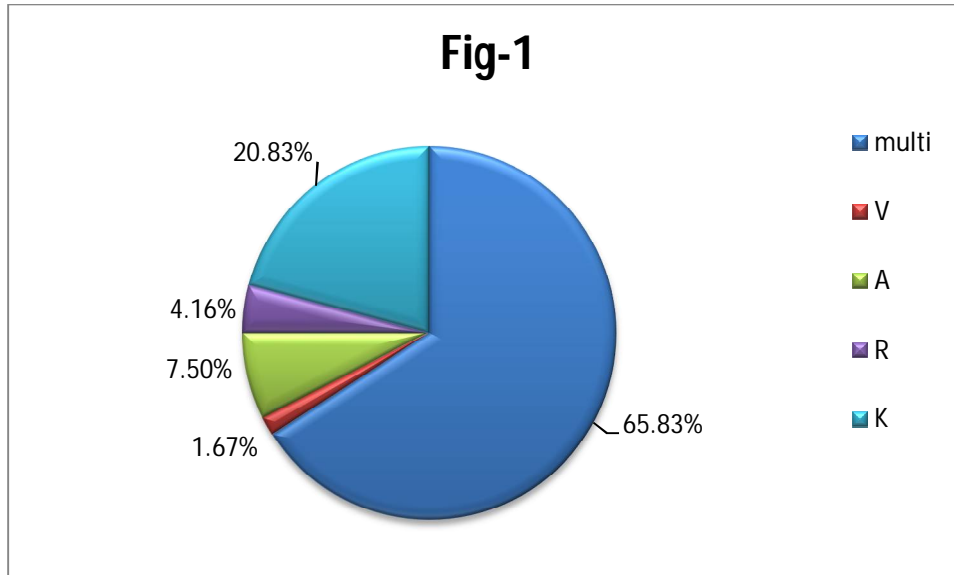


Fig-1 shows percentages of students who preferred visual ,auditory,reading/ writing kinesthetic and multiple modes of information presentation.

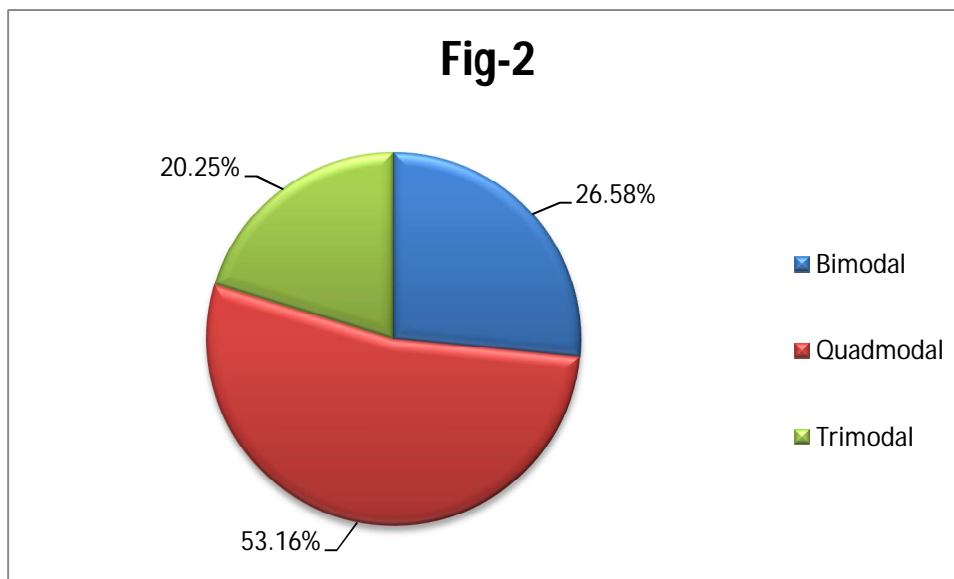


Fig-2 percentages of students who preferred two , three or four modes of information presentation.

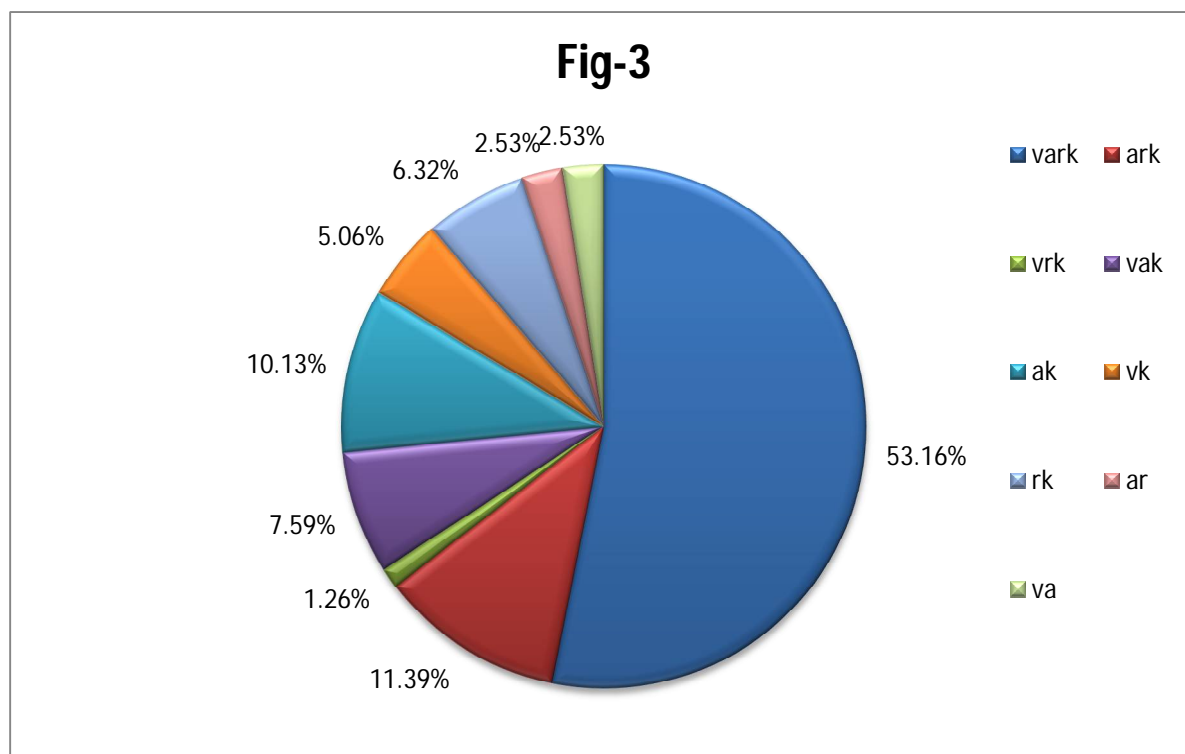


Fig -3 breakup of percentage of students who preferred three modes like VRK, VAK and ARK

And two modes like VA, AR, VK, RK and AK. VAR had zero preferences amongst trimodal students and VR had zero preferences amongst bimodal students and hence could not be represented in the pi chart.

3]

### **A CASE STUDY OF COMPARATIVE STUDY OF EPIDURAL ANESTHESIA USING 0.5% BUPIVACAINE AND 0.75% ROPIVACAINE IN CAESAREAN SECTION**

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#### **Abstract**

**Background:** Early studies suggested that Ropivacaine had clinical advantages over Bupivacaine with respect to cardio toxicity and motor block, and that it was suitable for epidural caesarean section. This study was set up to compare epidural 0.75% Ropivacaine with a popular 0.5% Bupivacaine for elective caesarean section.

**Methods:** 60 women having elective caesarean section under epidural anaesthesia were randomly allocated to receive 18- 20 mL of either 0.75% Ropivacaine or 0.5% Bupivacaine.. Times were recorded for onset of sensory block, density and duration of motor block, and the need for supplementation.

**Results:** The mean time taken to achieve sensory block at T10 was 9.33+/-2.54 min in group B and 11.33+/-2.60minutes in group R . . In group B 93.33% patients had achieved T10 level with in 10 min as against 76.67%in group R. In group B 6.67 % patients had achieved T10 level after 10 min as against 23.33 % patients in group R. However, Ropivacaine produced a motor block that was denser time to achieve modified bromage score 3 was 10 to 25 minutes in group and 10-30 minutes in group R . The mean time taken to achieve modified bromage score 3 was 15.83+/-2.96 minutes in group Band 16.33+/- 3.7 min in group R

**Conclusions:** This study suggests that epidural 0.75% Ropivacaine may be used as an alternative to

Bupivacaine 0.5% for elective caesarean section, with a denser and prolonged motor block. With the onset time of anaesthesia

Keywords: Epidural Anaesthesia; Caesarean section; bupivacaine; ropivacaine

### Introduction

Neuraxial analgesia is frequently administered to women in for LSCS. The choice of anaesthesia depends on the indications for the surgery , the degree of urgency , maternal status ( full stomach ) and the desire of the patient for the type of anaesthesia as well as whether to stay awake during child birth or not <sup>5</sup>.

Most caesarean section are now performed with single –shot spinal anaesthesia . Epidural anaesthesia provides segmental block of spinal sensory and sympathetic nerve fibres with partial block of motor fibres. Lumbar epidural analgesia is a gold standard and widely used technique for providing labour analgesia<sup>5</sup>.It can provide analgesia for both stages of labour and can be extended to provide anaesthesia for caesarean section or instrumental delivery if need arises. It has some advantages over spinal like lower incidences of hypotension ,lower risk of high spinal block since it provides segmental block , then there is no risk of post dural headaches , the risk os spinal cord injury is less , top of doses can be given to extend post operative analgesia though motor block is less pronounced

For many years, bupivacaine has been used because of its long duration of action, limited placental transfer, and minimal neonatal effects. Compared with older local anesthetics such as tetracaine, bupivacaine provided better analgesia without excessive motor block. In addition, compared with lidocaine, there was less tachyphylaxis with long-term administration. However, Bupivacaine is more cardio toxic than other local anesthetics and motor blockade accompanies the analgesia especially at higher concentrations. Many local anesthetics such as Bupivacaine exist in 2 forms, levorotatory and dextrorotatory. Ropivacaine is an amide local anesthetic produced in the pure levorotatory form. Its use may address some of the concerns related to bupivacaine.<sup>7,9,14</sup>

The **AIM of this study** was to assess whether there is an advantage to the use of either of these local anesthetics for neuraxial analgesia, so we compared 0.5% Bupivacaine with 0.75% Ropivacaine as local anaesthetic agents in caesarean section Sensory and motor blocking properties , hemodynamic properties and intraoperative and

postoperative complications and side effects of equal concentrations of Bupivacaine and Ropivacaine was compared .

### **Methods**

**Sixty** pregnant women posted for elective caesarean section were selected after taking written informed consent. All women ASA I or II, at P36 weeks of gestation over 18 years old were randomly allocated into two groups(n=30) each and received 18-20ml

Group B : Inj. bupivacaine. 0.5%

Group R : Inj Ropivacaine 0.75 %.

Women in labour, with known contraindication to regional anaesthesia like who had significant back surgery, injury or scoliosis, coagulopathy, psychiatric illness local infection and those known to have an allergy to amide local anaesthetics were **excluded**. Women in whom there was any concern about fetal wellbeing were also excluded.

All women were premedicated with oral ranitidine 150 mg and Ondansetron 8mg and On arrival in the Operation theatre were preloaded with Ringer lactate solution 500 mL intravenously. The epidural was performed by anaesthetist or with the patient in left lateral position. The epidural space was identified according to normal practice in the L2-3 or L3-4 interspace with a 18-gauge Tuohy needle, bevel cephalad, using a midline approach, with loss of resistance to either air or saline. An epidural catheter was inserted with 3 cm left in the epidural space, and patients were then positioned supine with approximately 15° uterine tilt to the left (ensuring that the abdominal bump looked displaced) . A second anaesthetist, not involved in the study, prepared and administered the study solution according to instructions found within a pre-randomised, sealed, numbered envelope. Subjects were randomly allocated to receive either 18- 20 mL of 0.75% ropivacaine (group R) or 18- 20 mL of 0.5% bupivacaine . Five minutes after a 3-mL test dose of 2% plain lidocaine had been given by the investigator, the study solution was given The solution was given slowly over 2 min . All assessments (preoperative, intraoperative and postoperative) were made The timing period for the study began once all the study solution had been given. Electrocardiogram (ECG) and pulse oximetry were started upon arrival in theatre. An automated sphygmomanometer recorded maternal blood pressures every 5 min. Hypotension (systolic pressure <100 mmHg, or a 20% drop from baseline, or symptoms of nausea, dizziness or faintness) was treated using additional fluids and/or ephedrine 3–6 mg boluses.

### **Evaluation**

**Sensory Block** : was assessed by using pinprick test every 5 min after injection of drug through epidural catheter till sensory block at T10 and after surgery every hourly till regression of sensory block below T10.

**Onset of sensory Blockade** : Time required to produce loss of pinprick sensation at dermatome at T10

**Duration of sensory block** : Time of regression of analgesia to pin prick below T10 dermatome

**Motor blockade** : It was assessed by using modified bromage score every 5 min after injection of drug through epidural catheter till patient was unable to perform straight leg rise (modified bromage score 3) and surgery every hourly till patient was able to perform straight leg rise test (modified bromage score 6)

### Modified Bromage score by Breen et.al<sup>1,2</sup>

- 1 Complete block (able to move hips, knees, feet and lift legs up)
- 2 Almost complete block(able to move knees and feet)
- 3 Partial Block (only able to move feet)
- 4 Detectable weakness of hip flexion while supine (full flexion of knees )
- 5 No detectable weakness of hip flexion while supine
- 6 Able to perform partial knee bend

During surgery, all women received oxygen (8 L min<sup>-1</sup>) via a mask until delivery of the baby, whereupon Syntocinon 10 units (in two divided doses) - were given intravenously.

#### Assessment

of the baby, according to obstetric and neonatologist protocol, included routine preoperative fetal heart monitoring using a cardiotocograph, Apgar scores at 1, 5 and 10 min after delivery .

The postoperative analgesic regimen used for all women was standard for this hospital at the time of

the study. This comprised 50mg tramadol via epidural route .At the end of surgery, time was noted . pulse rate blood pressure and level of sensory and motor blockade were evaluated hourly till six hours and then at 12 and 24 hours after surgery.

Time of regression of analgesia of analgesia to pin prick below T10 dermatome was considered as duration of sensory block and the time at which patient was able to perform straight leg rise was considered as duration of motor block .Nausea , vomiting , bradycardia , hypotension and urinary retention were assessed . Epidural catheter was removed 24 hours after surgery .

Data were analysed using unpaired 't'test with  $P < 0.05$  considered statistically significant and presented as mean values and mean  $\pm$  SD .

#### Results

Both groups were demographically comparable in terms of mean age (26.93yr,25.57yr), mean weight (62.63kg, 59.83 kg), mean height (152.53cm, 151.9 cm )in group Bupivacaine and Ropivacaine respectively.

**Table 1. Demographic Data**

Demographic Data	Group B (Mean $\pm$ SD)	Group R (Mean $\pm$ SD)
Age (years)	26.93 $\pm$ 3.96	25.57 $\pm$ 3.66



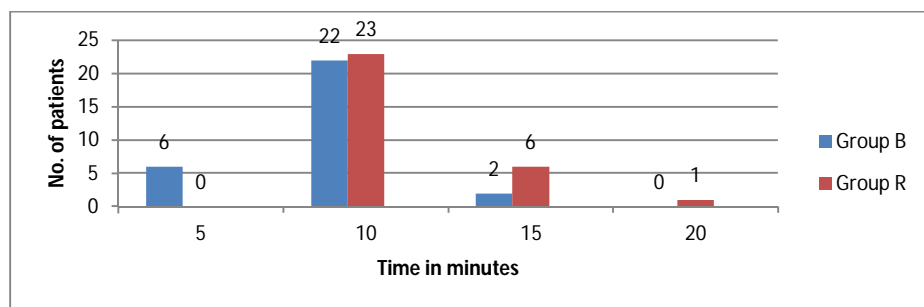
Weight (kg) 62.63±5.57 59.83±6.46

Height (cm) 152.53±5.33 151.9±5.52

**Table 2 : Time taken for onset of sensory block**

	Group B (no. of patients )	Group R (no. of patients )
5	6	0
10	22	23
15	2	6
20	0	1
<b>Total</b>	<b>30</b>	<b>30</b>
<b>Mean</b>	<b>9.33+/- 2.54</b>	<b>11.33+/-2.60</b>
<b>+/-</b>		
<b>SD</b>		

**Figure - 1 Time taken for onset of sensory block at T10**

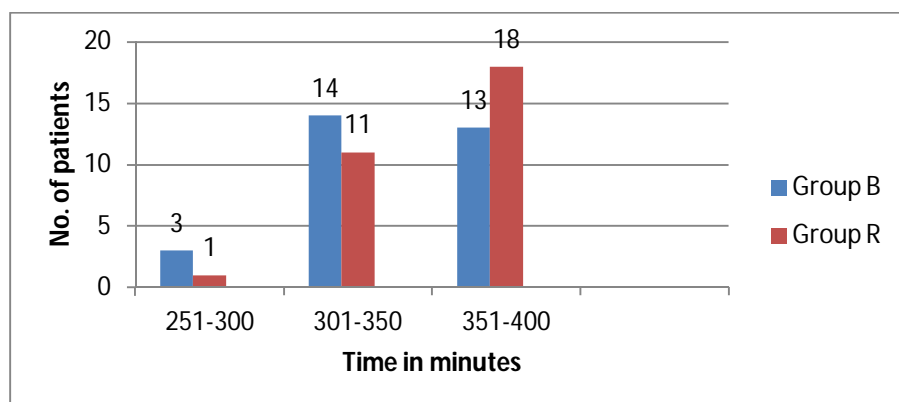


The range of time taken to achieve sensory block at T10 was 5-15 minutes in group B and 10-20 min in group R . The mean time taken to achieve sensory block at T10 was 9.33+/-2.54 min in group B and 11.33+/-2.60minutes in group R . . In group B 93.33% patients had achieved T10 level with in 10 min as against 76.67%in group R. In group B 6.67 % patients had achieved T10 level after 10 min as against 23.33 % patients in group R showing a statistically significant difference between the two groups (p <0.05).

**Table 3 Duration of Sensory Block**

Duration(min)	Group B (No. of patient)	Group R ( No. of patient)
251-300	3	1
301-350	14	11
351-400	13	18
<b>Total</b>	<b>30</b>	<b>30</b>
<b>Mean±SD</b>	<b>340.67±40.42</b>	<b>352.67±34.95</b>

**Figure 2 Duration of Sensory Block**



The range of Duration of sensory was 255 to 380 minutes in group B and 250 to 380 min in group R. The mean time for duration of sensory block was 340.67 +/-40.42 min and group B and 352.67 +/- 34.95 minutes in group R showing no statistically significant difference between the two groups ( P>0.05)

**Table 4 Time for onset of Motor Block**

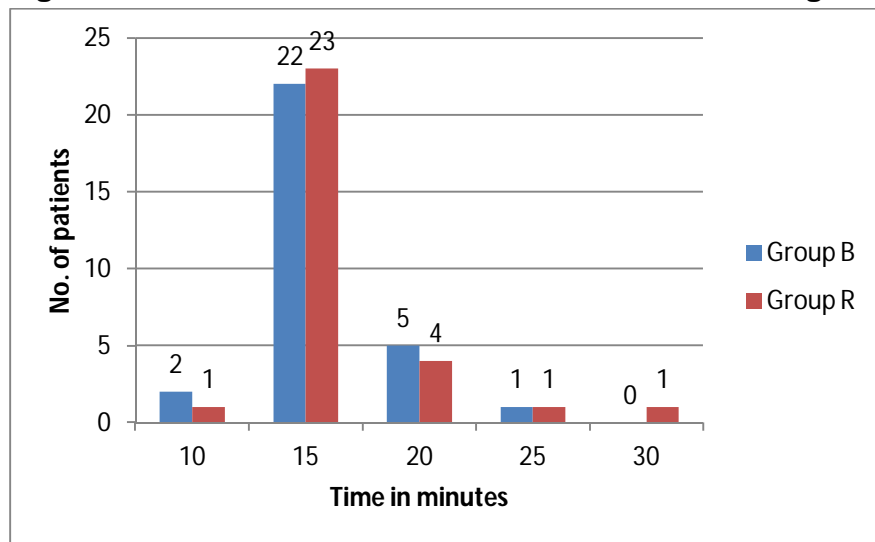
Time(min)	Group B (No. of patient)	Group R ( No. of patient)
10	2	1
15	22	23
20	5	4

25	1	1
30	0	1
Total	30	30

Mean±SD 15.83±2.96 16.33±3.7

t =0.5780, p=0.5655(>0.05) not significant

**Fig 3. Time for Onset of Motor Block Modified bromage score 3**



The range of time to achieve modified bromage score 3 was 10 to 25 minutes in group and 10-30 minutes in group R . The mean time taken to achieve modified bromage score 3 was 15.83+/-2.96 minutes in group Band 16.33+/- 3.7 min in group R showing no statistically significant difference between the two groups . p.0.05

**Table 5 Degree of motor block at the time of onset of sensory block at T10 by modified bromage score**

Modified bromage score	Group B (No. of patient)		Group R( No. of patient)	
	No.	%	No.	%
5	7	23.33	2	6.67
4	23	76.67	24	80
3	0	0	4	13.33
Total	30		30	

At time of onset of sensory block at T10, modified bromage score was 5 in 23.33% patients of group B and 6.67% patients of group R , 4 in 76.67 % of group B and 80 % of Group R and 3 in 0 patientof group B and 13.33 % of group R .

The range of duration of motor block was 185 to 375 minutes in group B 255 to 440 minutes in group R. the mean time for duration of motor block was 306.17 +/-47.83 min in group B and 369.67+/-42.51 min in group R showing a statistically significant difference between the two groups (p<0.05).

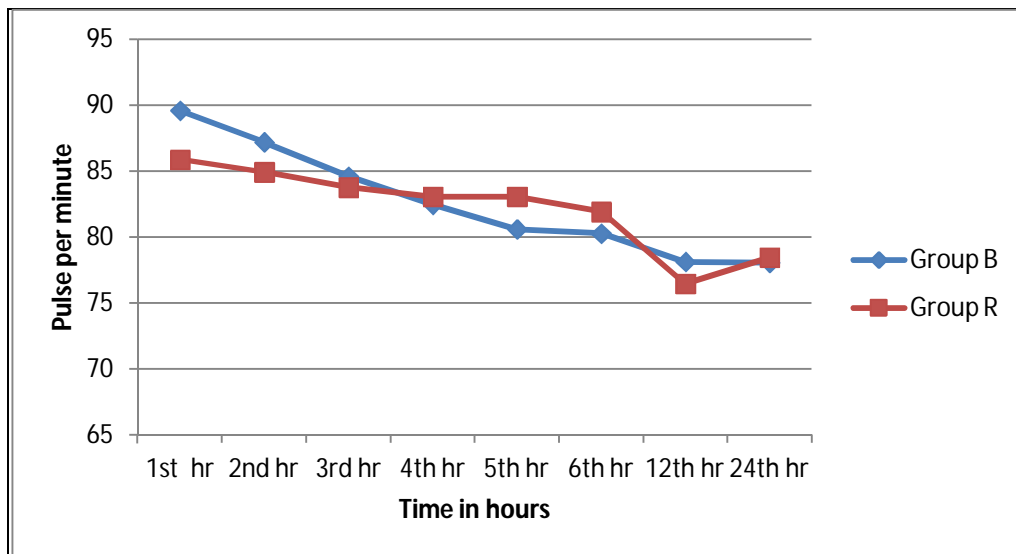
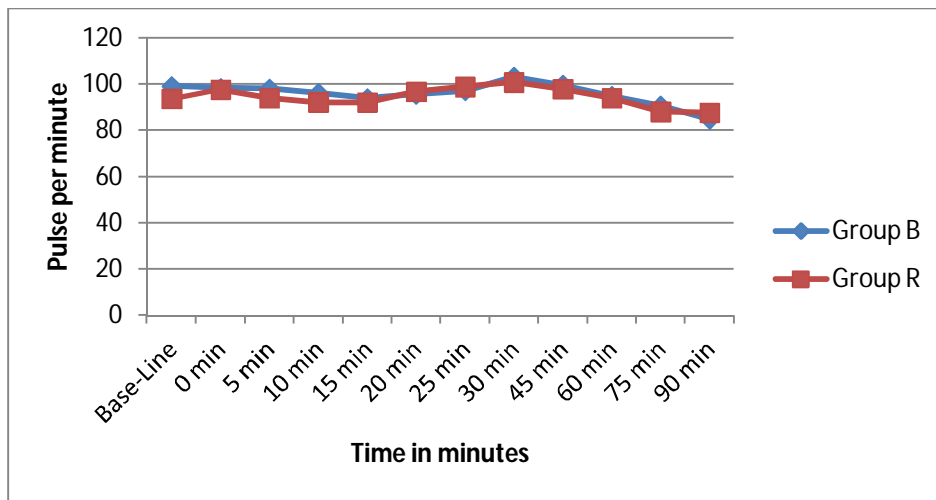
**Table 6 : Pulse Rate Changes**

Time interval	Group B		Group R		T Test	P Value
	Mean	±SD	Mean	±SD		
Base-Line	99.10	20.26	93.63	12.71	1.252	0.216
Intra Operative						
0 min	98.27	20.08	97.60	15.54	0.141	0.886
5 min	98.03	17.4	93.90	18.16	0.900	0.372
10 min	96.03	19.28	92.13	13.62	0.905	0.369
15 min	93.87	19.47	92.07	11.09	0.440	0.662
20 min	95.63	16.22	96.63	12.73	0.266	0.791
25 min	97.10	17.46	98.83	12.63	0.440	0.661
30 min	103.07	17.82	100.77	13.54	0.563	0.576
45 min	99.60	14.48	97.83	14.2	0.477	0.635
60 min	94.83	12.7	93.93	14.70	0.254	0.801
75 min	90.67	8.84	88.03	12.20	0.957	0.342
90 min	84.77	8.76	87.60	10.63	1.127	0.265
Post Operative						
1st hr	89.6	12.33	85.87	8.56	1.362	0.179
2nd hr	87.20	11.23	84.93	9.36	0.849	0.399
3rd hr	84.60	11.29	83.77	7.24	0.340	0.735
4th hr	82.47	9.58	83.07	5.45	0.298	0.767

5th hr	80.60	8.77	83.07	5.95	1.301	0.198
6th hr	80.27	6.55	81.93	4.41	1.156	0.253
12th hr	78.13	5.12	76.47	3.63	1.455	0.151
24th hr	78.07	5.32	78.47	4.48	0.315	0.754

The changes in pulse rate between the two groups were not statistically significant during intraoperative as well as post operative period

**Figure 4:intraoperative pulse rate changes**



**Figure – 5 Pulse rate changes during post op period**

Changes in Systolic blood pressure between the two groups were not statistically significant during intraoperative period  $p > 0.05$  but in post operative period at 2nd, 3rd and 4th hour, changes in systolic blood pressure between the two groups were statistically significant  $p < 0.05$

Figure 6: Changes in Systolic blood pressure

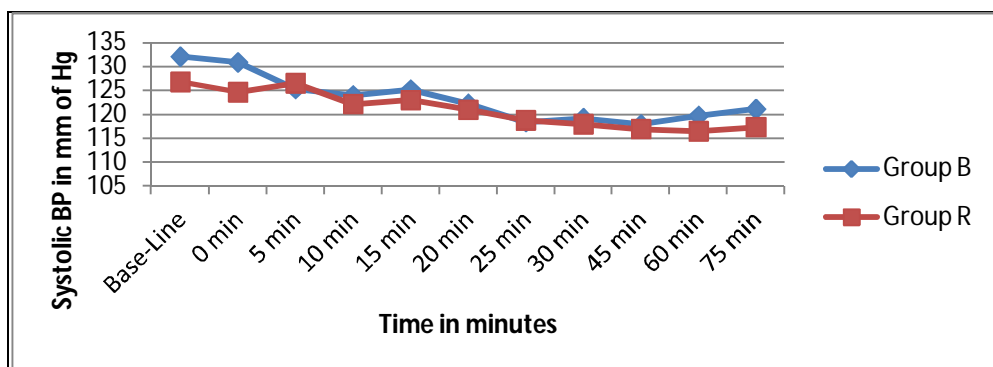


Figure – 7 Systolic Blood Pressure Changes during intra op period

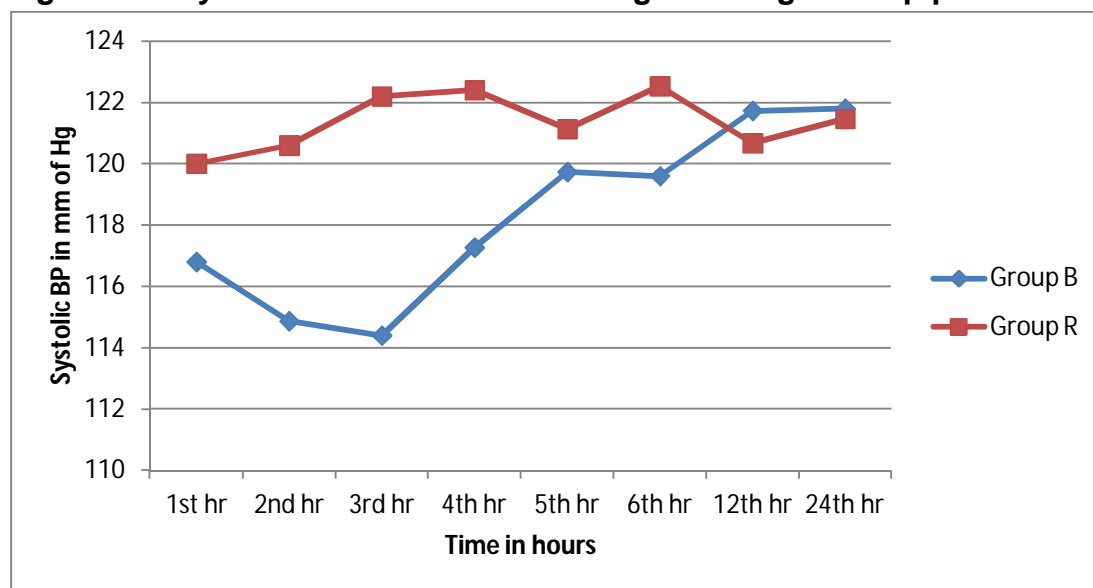
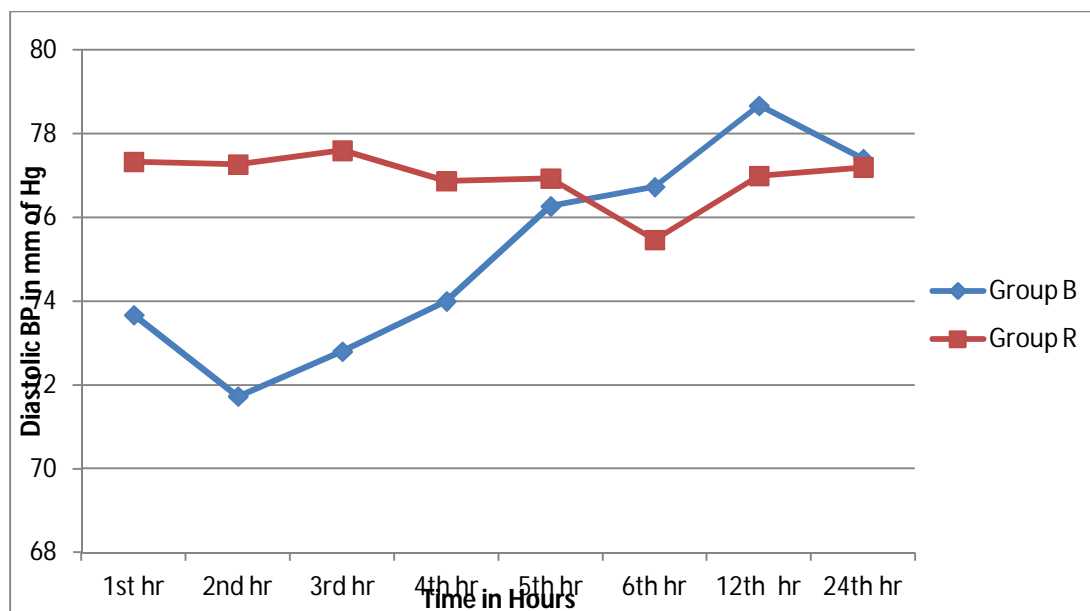


Figure – 8 Systolic Blood Pressure Changes during intra op period

Changes in diastolic blood pressure between the two group were not statistically significant during intraoperative period  $p > 0.05$  but in post operative period at 2nd and 3rd hour, changes in diastolic blood pressure the two groups were statistically significant  $p < 0.05$

Figure9: Diastolic Blood Pressure changes during post op period



**Side Effects** : During intraoperative hypotension was noted in one patient of both groups . there was no incidence of any other side effects in intraoperative period . no other side effects were noted in either group during post operative period like nausea vomiting hypotension ,bradycardia and urinary retention .

Side effects	Group B	Group R
Nausea/Vomiting	0	0
Bradycardia	0	0
Hypotension	1	1
Urinary retention	0	0

### Discussion

When ropivacaine was first released it was widely promoted as a potentially superior agent to bupivacaine because of lower toxicity and less motor block. Studies suggested that ropivacaine is less cardiotoxic than Bupivacaine. Ropivacaine is a long acting amide type local anaesthetic relased for clinical use in 1996 . In comparison with Bupivacaine it is equally effective for subcutaneous infiltration,epidural and peripheral nerve block for surgery , obstetric procedures and post operative analgesia . Ropivacaine because of its pure S- enantiomer form is less cardiotoxic than Bupivacaine . the motor blocking characteristics it is less potent than Bupivacaine . In our study , Both groups were demographically comparable in terms of mean age (26.93yr,25.57yr), mean weight (62.63kg, 59.83 kg), mean height (152.53cm, 151.9 cm )in group Bupivacaine and Ropivacaine respectively

**David L. Brown , Randall L.Carpenter, Gale E. Thompson**<sup>6</sup> observed onset of sensory block at T10 level in 10.7 +/- 5.6 min in 0.5% Ropivacaine and 13.0 +/- 10.7 min in 0.5% Bupivacaine, at T5 level in 20.5 +/- 7.9 in 0.5% Ropivacaine and 19.5 +/- 10.2 min in 0.5% Bupivacaine, duration of sensory block 333 +/- 54 min for Ropivacaine and 394 +/- min for Bupivacaine. Our study supports these in which, onset of sensory block at T10 was 9.33 +/- 2.55 min in group B and 11.33 +/- 2.60 minutes in group R . Duration of sensory block was 340.67 +/- 40.42 min in group B and 352.67 +/- 34.95 min in group R.

Increasing the concentration of Ropivacaine resulted in greater degree and longer duration of motor block . A positive correlation was noted between the total dose of Ropivacaine and the sensory block profile by **Brendan T. Finucane, et al in 1994**<sup>3</sup>, did a double – blind comparative study of Ropivacaine 0.5%, 0.75%, 1% and Bupivacaine 0.5%, in 125 patients of abdominal hysterectomy . It was the first study to test the efficacy of Ropivacaine when injected epidurally for major abdominal surgery . Increasing doses of Ropivacaine were associated with an increased clinical effect . The main difference between Ropivacaine 1.0 % and Bupivacaine 0.5% was in sensory duration and between different doses of Ropivacaine in motor duration.

Our study supports this Duration of motor block for 0.75 % Ropivacaine is longer and more intense . The mean time taken to Ropivacaine is longer and more intense . The mean time taken to achieve modified Bromage score 3 was comparable in both groups . Degree of motor block was observed and considered as the modified Bromage score at that time of onset of sensory block at T10 . It was 5 in 23.33% patients of group B and 6.67% patients of group R, 4 in 76.67% of group B and 13.33% of group R at time of onset of sensory block.

The range of duration of motor block was 185 to 375 minutes in group B and 255 to 440 min in group R . The mean time for duration of motor block was 306.17 +/- 47.83 min in group B and 369.67 +/- 42.51 min in group R which was statistically significant  $p < 0.05$

**In 2005 , N.Christelis , J. Harrad , P.R Howell**<sup>10</sup> did a comparative study of epidural Ropivacaine 0.75% and Bupivacaine 0.5% fentanyl mixture for elective caesarean section .and suggested that epidural 0.75% ropivacaine without opioid could be used as an alternative to bupivacaine 0.5% with fentanyl for elective caesarean section, but it did not induce anaesthesia any faster but resulted in a denser, more prolonged, motor block our study supported this study .

**In 2011, Sara Korula, et al**<sup>13</sup>, found that duration and intensity of motor block with 0.75% Ropivacaine was comparable to 0.5% Bupivacaine .

In our study we found that epidural 0.5% Bupivacaine and 0.75% were similar in both sensory and motor blocking characteristics for Caesarean section , with the exception that Ropivacaine produced slightly longer and dense motor blockade . As Ropivacaine is less cardiotoxic and neurotoxic than Bupivacaine , it is recommended for epidural anaesthesia in caesarean section .



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#### 4] STUDY OF ORAL CLONIDINE PREMEDICATION IN LAPAROSCOPIC SURGERIES

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#### ABSTRACT

Clonidine has anti-hypertensive properties and augments the effects of anaesthesia, so it is considered to be an ideal agent to reduce the stress response to pneumoperitoneum in laparoscopic surgeries. The aim of the study was to investigate the clinical efficiency of oral clonidine premedication in prevention of haemodynamic response associated with pneumoperitoneum. Clonidine premedication provides perioperative haemodynamic stability, hence it can be recommended as a routine premedication for laparoscopic procedure.

**KEY WORDS** :Laparoscopic surgeries; Pneumoperitoneum, Haemodynamic response; Clonidine premedication.

#### INTRODUCTION

Laparoscopic surgeries has now become the “gold standard”. It offers many benefits than conventional surgeries and promoted as a “gentle surgery”.<sup>[1]</sup> However, it is not risk free. It produces significant haemodynamic changes specially in elderly and haemodynamically compromised patients.<sup>[2]</sup>

The hallmark of laparoscopy is creation of carbon dioxide (CO<sub>2</sub>) pneumoperitoneum and change in the patient’s position from Trendelenberg to reverse Trendelenberg. Pneumoperitoneum(Pnp) affects several homeostatic systems leading to alteration in acid-base balance, cardiovascular, pulmonary physiology and stress response.<sup>[3]</sup> The extent of cardiovascular changes associated with pneumoperitoneum include an increase in mean arterial pressure, decrease in cardiac output and increase in systemic vascular resistance which in turn compromise tissue perfusion.<sup>[4]</sup>

Various pharmacological agents like nitroglycerine, adrenergic receptor agonist, dexmedetomidine, clonidine were chosen to prevent haemodynamic changes associated with pneumoperitoneum.<sup>[2,4]</sup>

Clonidine is an  $\alpha$ -2 adrenoreceptor agonist.<sup>[5]</sup> It exerts central sympatholytic effect and has a half life of 9-12 h. Premedication with clonidine blunts the stress response to surgical stimuli and intubation. The narcotic and anaesthetic doses are also reduced.<sup>[6]</sup> In addition, clonidine increases cardiac baroreceptor reflex sensitivity to increase in systolic blood pressure, and thus stabilises blood pressure. Clonidine inhibits the

release of catecholamine<sup>[7]</sup> and vasopressin and thus modulates the haemodynamic changes induced by pneumoperitoneum.

Considering all these observations, the present study was designed to evaluate the type and extent of haemodynamic changes associated with laparoscopic surgery and also to find out the efficacy of clonidine in prevention of such haemodynamic changes.

## METHOD

50 adult patients of ASA physical status I & II, scheduled for elective laparoscopic surgeries were recruited for a prospective randomized, single-blinded comparative study. The study was approved by the institutional Ethical Committee and written informed consent was obtained from all the patients before being included in the study. They were randomly allocated to one of the two groups to receive either with oral clonidine 150 µg (Group A) or without oral clonidine (Group B), 60 minutes before induction of anaesthesia.

On arrival in the operation theatre, monitors were attached and baseline parameters such as heart rate, blood pressure and peripheral oxygen saturation were noted down. Level of sedation (sedation score) was assessed by sedation scale : (1) awake and agitated (2) awake and comfortable (3) asleep but arousable (4) asleep with sluggish response to persistent call or touch and (5) no response to call or touch.

After intravenous cannulation, glycopyrrolate 0.2 mg and fentanyl citrate 1 µg/kg i.v. given. Patients were induced with thiopentone sodium 5-7-mg/kg and succinylcholine 2mg/kg and endotracheal intubation was done. Anaesthesia was maintained with oxygen, nitrous oxide, sevoflourane and vecuronium bromide 0.1 mg/kg.

Pneumoperitoneum was created by insufflation of Carbon dioxide. Intra abdominal pressure (IAP) was not allowed to exceed 15 mm Hg throughout the surgical procedure. Ventilation was done to maintain end tidal carbon dioxide between 35-45 mm Hg. Systemic arterial pressure including the systolic, diastolic and mean arterial pressure, heart rate, SpO<sub>2</sub>, EtCO<sub>2</sub> were recorded at the following points of time : (1) prior to induction (2) during intubation (3) 3 minutes after endotracheal intubation (4) before pneumoperitoneum (5) five minutes after pneumoperitoneum (6) ten minutes after pneumoperitoneum (7) fifteen minutes after pneumoperitoneum (8) thirty minutes after pneumoperitoneum (9) five minutes after exsufflation of gas and (10) ten minutes after extubation.

Significant rise in heart rate was observed following pneumoperitoneum in Group B as compared to Group A ( $98 \pm 9.1$  Vs  $84.44 \pm 5.7$  bpm). Similarly, rise in systolic arterial pressure ( $124.96 \pm 7.0$  Vs  $150.6 \pm 3.8$  mm Hg), diastolic arterial pressure ( $94.04 \pm 3.8$  Vs  $79.1 \pm 3.6$  mm Hg) and mean arterial pressure ( $112.7 \pm 3.2$  Vs  $94.2 \pm 4.1$  mm Hg) was more in Group B following pneumoperitoneum.

At the end of surgery residual neuromuscular block was assessed and reversed by appropriate dose of glycopyrrolate and Neostigmine intravenously. Patients were extubated and transferred to recovery room, where they were monitored for complications or adverse events.

## Results

Demographic profile and preoperative vital parameters were compared among the two groups of patients and no significant difference was found (Table 1 & 2).

**Table 1 Demographic profile (Mean  $\pm$  SD)**

	<b>Gr A</b>	<b>Gr B</b>	<b>P Value</b>
<b>Age</b>	39.84 $\pm$ 13.60	42.4 $\pm$ 10.65	0.27
<b>Sex(M:F)</b>	9:16	8:17	

**Table 2 Preoperative vital parameters (Mean  $\pm$  SD)**

<b>Parameters</b>	<b>Gr A</b>	<b>Gr B</b>	<b>P value</b>
Pulse	85.48 $\pm$ 8.4	84.08 $\pm$ 9.0	0.5736
SBP	125.8 $\pm$ 10.4	124.6 $\pm$ 11.1	0.7055
DBP	79.2 $\pm$ 6.6	82.2 $\pm$ 6.5	0.1153
MAP	94.5 $\pm$ 7.3	96.2 $\pm$ 7.3	0.4375

Sedation

**Table 3 Changes in pulse rate in two groups**

**Changes in Pulse Rate(bpm)**

	<b>HR of gr A (Mean<math>\pm</math>SD)</b>	<b>HR of gr B (Mean<math>\pm</math>SD)</b>	<b>p value</b>
1 hr prior to sx	85.48 $\pm$ 8.4	84.08 $\pm$ 9.0	0.5736
before intubation	81.84 $\pm$ 6.2	85.76 $\pm$ 9.5	0.094
during intubation	92.88 $\pm$ 6.6	101.16 $\pm$ 9.7	<0.005
3 min after intubation	86.04 $\pm$ 6.5	95.16 $\pm$ 9.2	<0.005

10 min after intubation	83.56±7.8	94.4±10.3	<0.005
before pneumopertonium	83.16±6.9	93.68±8.9	<0.005
5 min after pneumoperitonium	84.04±5.8	97.96±10.1	<0.005
10 min after pneumoperitonium	84.44±5.7	98±9.1	<0.005
15 min after pneumoperitonium	83.4±6.6	96.24±9.5	<0.005
30 min after pneumoperitonium	82.76±7.0	98.04±5.9	<0.005
5 min after exsufflation	83.48±5.7	92.72±9.0	<0.005
During Extubation	90.88±5.9	99.6±8.1	<0.005
5 min After Extubation	83.36±5.7	93.48±8.1	<0.005

**Table 4 Changes in systolic blood pressure in two groups**

**Changes in SBP(mm Hg)**

	<b>SBP of gr A (Mean±SD)</b>	<b>SBP of gr B (Mean±SD)</b>	<b>p value</b>
1 hr prior to sx	125.8±10.4	124.6±11.1	0.7055
before intubation	122.72±10.8	125.2±10.6	0.4106
during intubation	134.56±10.0	144.8±8.9	<0.005
3 min after intubation	126.76±9.3	140.8±10.6	<0.005
10 min after intubation	123.08±9.7	137.04±9.9	<0.005
before pneumopertonium	122.92±8.2	136.44±9.4	<0.005
5 min after pneumoperitonium	126.48±10.6	141.6±11.2	<0.005
10 min after pneumoperitonium	124.96±7.0	150.6±3.8	<0.005

15 min after pneumoperitonium	123.56±8.3	155.6±4.8	<0.005
30 min after pneumoperitonium	122.92±7.5	152.7±3.2	<0.005
5 min after exsufflation	123.72±7.6	130.7±8.0	<0.005
During Extubation	132.64±7.4	140.68±7.4	<0.005
5 min After Extubation	123.32±7.8	133.08±7.1	<0.005

**Table 5 Changes in mean arterial pressure in two groups**

**Changes in MAP(mm Hg)**

	<b>MAP of gr A (Mean±SD)</b>	<b>MAP of gr B (Mean±SD)</b>	<b>p value</b>
1 hr prior to sx	94.5±7.3	96.2±7.3	0.4375
before intubation	92.4±7.6	96.7±7.0	0.0426
during intubation	102.0±6.9	110.7±5.9	<0.005
3 min after intubation	95.5±6.0	107.3±6.9	<0.005
10 min after intubation	93.3±6.3	104.9±7.3	<0.005
before pneumopertonium	93.6±4.9	104.2±6.7	<0.005
5 min after pneumoperitonium	95.0±5.6	107.6±8.1	<0.005
10 min after pneumoperitonium	94.2±4.1	112.7±3.2	<0.005
15 min after pneumoperitonium	93.3±4.5	116.2±4.7	<0.005
30 min after pneumoperitonium	93.1±4.3	114±4.2	<0.005
5 min after exsufflation	93.4±4.3	99.8±5.8	<0.005
During Extubation	100.6±4.9	107.2068±5.4	<0.005
5 min After Extubation	92.9±5.3	101.1±5.0	<0.005

**Table 6 Changes in diastolic blood pressure in two groups****Changes in DBP(mm Hg)**

	<b>DBP of gr A (Mean±SD)</b>	<b>DBP of gr B (Mean±SD)</b>	<b>p value</b>
1 hr prior to sx	79.2±6.6	82.2±6.5	0.1153
before intubation	77.4±6.5	82.6±6.2	0.0061
during intubation	86.0±6.1	93.8±5.4	<0.005
3 min after intubation	80.1±4.9	90.8±6.2	<0.005
10 min after intubation	78.6±5.2	89.2±7.1	<0.005
before pneumoperitonium	79.1±3.6	88.2±6.9	<0.005
5 min after pneumoperitonium	79.5±4.2	91.04±8.5	<0.005
10 min after pneumoperitonium	79.1±3.6	94.04±3.8	<0.005
15 min after pneumoperitonium	78.4±4.1	98±3.1	<0.005
30 min after pneumoperitonium	78.4±3.8	96.04±3.1	<0.005
5 min after exsufflation	78.5±3.6	84.68±6.2	<0.005
During Extubation	84.8±4.2	90.7±5.6	<0.005
5 min After Extubation	77.92±4.4	85.32±5.4	<0.005

**Table 7 Changes in etco2 in twogroups****6) Changes in etco2**

	<b>Mean Etco2of cases</b>	<b>Mean Etco2of control</b>	<b>p value</b>
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1 hr prior to sx	-	-	-
before intubation	-	-	-
during intubation	-	-	-
3 min after intubation	29.4±0.9	29.6±1.8	0.36
10 min after intubation	30.6±1.4	30.9±1.2	0.4
before pneumoperitonium	30.3±1.1	30.5±0.8	0.49
5 min after pneumoperitonium	31.1±1.3	31.6±1	0.2
10 min after pneumoperitonium	31±1.6	31.7±0.9	0.07
15 min after pneumoperitonium	30.7±1.6	31.3±1.2	0.14
30 min after pneumoperitonium	31.6±1.7	31.8±1.1	0.56
5 min after exsufflation	29.8±1	29.9±0.7	0.54
During Extubation	-	-	-
5 min After Extubation	-	-	-

**Table 8 Post operative monitoring**

	<b>Gr A</b>	<b>Gr B</b>
Nausea- Vomiting	4	2
Sedation (sedation score)	8	27
1	20	3
2		
3	2	



## Discussion

Pneumoperitoneum during laparoscopy produces significant haemodynamic changes, which can be detrimental especially in elderly and in haemodynamically compromised patients. Various techniques and pharmacological agents have been used to counteract these detrimental effects of pneumoperitoneum.

This single blinded prospective study was carried out in 50 adult patients, to evaluate the effect of clonidine premedication in attenuating haemodynamic stress response associated with intubation and pneumoperitoneum.<sup>[3]</sup>

Clonidine, an imidazoline derivative is a selective  $\alpha$ -2 adrenergic agonist. It produces a fall in the heart rate and blood pressure associated with decreased SVR and cardiac output.<sup>[8]</sup> 100  $\mu$ g clonidine was administered orally, 60 minutes before surgery. In operation theater standard monitoring devices were applied. Inj. glycopyrrolate and Inj. Fentanyl 1  $\mu$ g/kg were given and patients were induced with pentothal sodium and Succinyl choline and maintained with oxygen, nitrous oxide, sevoflourane and vecuronium bromide 0.1 mg/kg. all throughout surgeries haemodynamic parameters were monitored. Following pneumoperitoneum with carbon dioxide, patients were hyperventilated to maintain normocapnia. Intra abdominal pressure (IAP) was maintained below 14 mm Hg.

Following intubation and pneumoperitoneum, increase in arterial pressure was noticed but it never crossed more than 30% of baseline value in group A. Hence clonidine premedication was able to achieve haemodynamic stability during pneumoperitoneum.<sup>[9,10,11]</sup>

The adverse effects in the postoperative period were less in the patients who had clonidine premedication in comparison with placebo premedication.

In conclusion, premedication with 150  $\mu$ g oral clonidine, has been found to be relatively safe as well as effective method that provides stable haemodynamics and protection against stress response triggered by pneumoperitoneum in patients undergoing laparoscopic surgeries. Clonidine also affords an added advantage of reduction in postoperative complications such as nausea-vomiting. Hence 150  $\mu$ g oral clonidine can reasonably be recommended as premedication for all laparoscopic procedures in otherwise healthy patients.

## SUMMARY

To conclude, the administration of oral clonidine 150  $\mu$ g as a simple and cost effective form of premedication in patients undergoing laparoscopic surgeries. It has good perioperative haemodynamic stability.

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## 5

### **”EFFECTS OF LOWER LIMB EXERCISE IN OLD AGE GROUP IN BERG BALANCE SCORE”**

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## **ABSTRACT**

Falls are a relatively common event in older people. Approximately 30% of individual's over 65 years of age fall at least once a year, and about half of those do so recurrently. Fall related injuries and death in older people are a major health care problem worldwide, with the numbers continuing to rise. Thus, falls prevention in older people remains a major health care priority. In the old age group muscle weakness, joint stiffness, proprioceptive deficit is very common which leads to imbalance and ultimately increasing the risk for fall. Fall itself is very hazardous for the old age group as bone density will be reduced and can cause fracture of upper limb or lower limb bone. So it is highly advised that weight bearing exercise like one leg standing, tandem walking as well as functional strengthening exercises like forward lunges, mini squatting and stepping exercises can be very helpful for the older individual which increases the balance and strength in the lower limb and reduces the chances of fall.

## **1: INTRODUCTION**

Falls are a relatively common event in older people. Approximately 30% of individual's over 65 years of age fall at least once a year, and about half of those do so recurrently. Fall related injuries and death in older people are a major health care problem worldwide, with the numbers continuing to rise. Thus, falls prevention in older people remains a major health care priority.

**FEAR OF FALLING (FoF)**, defined as a disabling symptom of impaired mobility among frail older people, is common in community of older adults. It has been associated with depression, functional limitations, and gait impairments.<sup>1</sup> FoF has been identified as one of the greatest fears experienced and felt by the older individual in the current era.<sup>2</sup>

Delbaere et al.<sup>3</sup> discussed the "vicious cycle" of FoF: those with FoF exhibit decreased activity and participation in their environment, leading to further decreases in strength and balance, thus placing them at greater risk for falls and increased FoF.

Development of FoF has been associated with worsening in performance of activities of daily living, mobility, mood, life satisfaction, and general health<sup>4, 5</sup>. Further, it has been shown to limit participation within roles and diminish social functioning, self-efficacy, and quality of life.<sup>6, 7</sup>

Rapid increase in the number of older people is a global phenomenon. Developing countries are graying as the elderly population is growing much faster than expected. An unprecedented increase in human longevity was one of the most spectacular events of the 20th century. The resultant population aging with all its ramifications is more evident in most parts of the world.<sup>8</sup>

Aging is a universal phenomenon. India is the second largest country in the world, with 72 million elderly persons above 60 years of age as of 2001.<sup>10</sup> World health organization (WHO) uses 60 years of age and older as the general definition of an older person. However an elderly can be defined in three main categories 1) chronology 2) change in social role (i.e. change in work patterns adults status of children and menopause) 3) change in capabilities (i.e. change in physical characteristics).<sup>9</sup> Aging is a cumulative and continuous process taking place in human from conception to death. This age group is classified as young old group between 60-75 years, middle old group between 75-85 years; old old group is older than 85 years of age.<sup>11</sup> With advancing age, structural and functional deterioration occurs in most physiological systems; this age related physiological changes affect a broad range of tissues, organ, systems and functions, which cumulatively can impact activities of daily living (ADL) and the preservation of physical Independence in older adults.<sup>12</sup>

According to Bowen RL, Atwood CS 2004 human body composition changes with age, but the causes and consequences of these changes are only partly understood. One such serious and a silent problem with which an elderly suffers is frailty syndrome. Rockwood et.al described the concept of frailty as “a multidimensional syndrome which involves loss of reserves (energy, physical activity, cognition and health) which gives rise to increased vulnerability.”<sup>14</sup> Subjects with the frailty syndrome

have increased risk of adverse events such as death, disability, and institutionalization.<sup>13</sup> Loss of muscle strength in old age is a prevalent and disabling condition. Muscle strength declines with age such that, on average the strength of people in their 80 years is about 40 percent less than that of people in their 20 years. Muscle weakness particularly of the lower limbs, is associated with reduced walking speed, increased risk of disability and falls in older people.<sup>16</sup>

This decline that is increasingly recognized to have important consequences in old age was given the name “sarcopenia” by Rosenberg (1989).<sup>17</sup> Sarcopenia is a syndrome characterized by progressive generalized loss of skeletal muscle mass and strength, usually accompanied by physical inactivity, decreased mobility, slow gait speed and poor physical endurance which are also common features of the frailty syndrome.<sup>14</sup> Sarcopenia is an important independent predictor of disability linked to poor balance, gait speed, and falls thus, leading to functional disability.<sup>13</sup>

Effect of aging and the subsequent loss of strength have a pronounced effect on the capacity of older people to lead viable and independent lives. The deterioration in functional capacity can decrease the ability to perform common activities of daily living in the older population. A recent study in the United States showed that above the age of 65, 28% of the men and 66% of the women could not lift objects weighing more than 4 kg, so, the viability of the musculoskeletal system definitely declines with age.<sup>18</sup> Prevalence of fall and fear of falling is potentially increasing with age, of the medical conditions predisposing to falls in elderly, musculoskeletal problems ranks first followed by others.<sup>15</sup> Disability in Activities of Daily Living (ADL), such as bathing, dressing, walking which are the essential activities that a person needs to perform to be able to live independently.<sup>20</sup> Disability can be identified accurately through responses to a wide variety of questions about the ability to perform activities ranging from basic self-care to household activities.<sup>21</sup> Disability in the older population, and the attendant need for informal and formal care, will increasingly affect older people, their families, and the health care system as the population continues to age.<sup>20</sup>

The performance of all activities of daily living requires good balance control while at rest or when moving from one position to another. Maintenance of balance requires the coordination of sensory, neural and musculoskeletal systems. Many of these systems undergo deterioration as people age. This has the potential to affect balance, restrict safe mobility, increase the likelihood of a fall and adversely affect quality of life. Therefore the assessment of balance with older people is important to direct appropriate interventions to improve balance performance and to monitor changes in balance over-time.<sup>22</sup>

Various approaches to measure balance have been developed. Questionnaires such as Rivermead Mobility Index and the Activities Specific Balance Scale provide self-report information regarding functional status. Laboratory measures such as computerized force platforms provide accurate measurements of postural sway. Functional performance-based tests such as the Berg Balance Scale and the Timed Up and Go Test may be defined as tests which objectively measure a person performing balance or walking tasks. An advantage of functional balance tests is their practicality for assessment in a variety of settings because of their low cost, lack of complex equipment and time efficacy.<sup>22</sup>

There are vast numbers of functional balance assessment tests. To measure the risk of fall in older people around 17 functional outcomes, like Functional Reach Test (FRT), Berg Balance Scale (BBS), Lateral Reach Test (LRT), Performance Oriented Mobility Assessment (POMA), Fullerton Advanced Balance Scale (FAB), Timed Up and Go Test (TUGT) Physical Mobility Scale (PMS), Balance Screening Tool (BST) etc are available. Of the numerous functional balance tests available, only the TUGT, BST, BBS and FAB have established reliability and concurrent validity with community dwelling older adults. TUGT and BST provide efficient screen of a person's balance abilities, however do not offer enough detail to determine the source of impairment. The FAB scale may be more applicable for older people living independently, however further research with higher methodological quality is required to establish its reliability

and validity. While being the most rigorously developed functional assessment balance test, the BBS may be more appropriate for use for frail older adults due to limited assessment of dynamic balance.<sup>22</sup>

It has been shown that individuals prone to falls possess lesser strength and power in their lower extremity as compared to those without a history of falls. It has been shown that 6 week of progressive resistance training program is likely beneficial for improving static and single leg stance balance in untrained older adults.<sup>24</sup> so, in geriatric population functional disability is the major problem. The evaluation of functional disability focuses on the performance of activities and functions in different areas, among which the tasks of everyday life, and other requisitions of the day to day activity.<sup>19</sup>

The association between reduced lower extremity strength, poor mobility and functional dependence in frail elders are well known. Older person's functional mobility performance and independence can be improved by enhancing lower extremity muscle function. Hip extension, knee extension, and planter flexors are significant predictors of ambulation functions in older adults in the community. Planter flexors and quadriceps muscle accounts for 42% to 59% of variance as being important determinant of ambulation capacity in community dwelling elderly fallers. They provide stability for the weight bearing limb and allow for advancement of the swinging limb in both walking and stair climbing tasks.<sup>23</sup> so, to measure physical dysfunction power is a reliable measure of muscle performance in younger and older individuals. The significance of impairments in muscle power has been demonstrated in studies confirming the positive association between muscle power and functional mobility tasks and the identification of peak muscle power as a strong physiological predictor of functional limitations and disability in older people.<sup>25</sup>

In 1980's it was thought that resistance training for older adults would only be beneficial for neural adaptation and that older muscles are unable to hypertrophy,

however in the next decade Frontera et. al., (1988) and Fiatarone et. al., (1990) clearly established by the more sophisticated imaging techniques in their studies that older adults could achieve muscle hypertrophy with short term (8-12 week) high intensity training. Recent studies show that resistance training has remarkable beneficial effects on the musculoskeletal system including prevention and treatment of this syndrome. Studies demonstrate that regular progressive resistance training develops the strength and size of muscle and increase bone mass from young male athletes to older women.<sup>13</sup>

PRT is the most commonly used resistance therapy in older people. Progressive resistance exercise is a method of increasing the ability of muscles to generate force and improves the physical function in elder people.<sup>29</sup> A Cochrane review of 121 randomized controlled trials of PRT 2-3 times per week improved physical function, gait speed, timed get up go score, climbing stairs, balance and more importantly had a significant effect on muscle strength especially in the high intensity training group.<sup>14</sup>

Sigrid Tieback et.al., described the PRT for older hospitalized patients have an effect on functional status, there is a significant improvements in the 10m walk test, barthel index and timed get up and go test after 8 week of resistance training with 2-3 session per week.<sup>11</sup> Daily adjusted progressive resistance exercise protocol is used for the special consideration like osteoporosis, geriatric population, children and pregnant women.<sup>28</sup> The DAPRE system is a 5-RM to 7-RM (repetition maximum), 4-set system. DAPRE allows patients to exercise to their fullest potential while simultaneously accounting for daily variations in their strength levels. With excessive resistance The DAPRE system allows for maximum strength gains to be attained in the quickest amount of time possible without endangering the patient by overloading his or her tissues and joints.<sup>29</sup> The DAPRE system provides our patients with a simple and reliable means of advancing their exercises that ensures they receive the desired benefits of the exercise without the worry that they will overload their tissues and reinjure themselves. It also provides a safety net for apprehensive patients who may be less inclined to advance their exercises due to fear of re injury. The DAPRE system is a reliable, valid,



and flexible tool that can be adjusted to a myriad of patients and rehabilitation settings and is a valuable resource for rehabilitation professionals.<sup>29</sup>

Balance is staying upright and steady when stationary, such as when standing or sitting, or during movement. The loss of ability to balance may be linked with a higher risk of falling, increased dependency, illness and sometimes early death. However, it is unclear which types of exercise are best at improving balance in older people living at home or in residential care.

So it is very important to see that how far physical therapy in the form of strengthening and stability exercise is helpful to improve the balance in the older age group. So many studies have been done to find out the relationship between berg balance scale and the strength in the lower limb. However in this study the aim was to find out specific exercise and finding out its effects on the score of balance.

## **2: METHOD**

### **2.1: DESIGN:**

We have taken 6 weeks exercise programme to see the effects on BBS before and after the exercise programme.

### **2.2: PARTICIPANTS:**

All 40 participants were assessed with BBS and their score was note down. Participant were chosen from the different cities of Gujarat and given full detail regarding the BBS and how score was counted.

### **2.3: INCLUSION & EXCLUSION:**

#### **2.3.1: Inclusion criteria:**

- *Age between 50 to 75*
- *Person should be willing to participate in the study*

#### **2.3.2: Exclusion criteria:**

- *Age more than 75*
- *Any associated musculoskeletal illness like severe osteoarthritis, severe ankle or hip pain*
- *Person is not willing to participate in the study*

#### **2.4: ASSESSMENT:**

Each individual was assessed and instructed in detail regarding the study purpose and the procedure by the final year students of the government physiotherapy college, Jamnagar, Gujarat.

Assessment was done by the BBS. It has 14 items and each item has score from 0 to 4 so minimum score can be 0 and the maximum score can be 56. If the score is high then it indicates that the balance is good and if score is less then balance is poor.

If BBS score is less than 36 points then there is risk of fall.<sup>30</sup>

#### **2.5: INTERVENTION:**

Exercise interventions designed for improving balance are typically those in which participants exercise in standing and moving positions of increasing difficulty so as to challenge the body's ability to anticipate and respond to the demands of different tasks or environments (Winter 1995). For balance to improve, participants have to exercise their muscles (and neuromuscular responses) against an external force, as a consequence of voluntary movement, or in response to an unexpected perturbation/stimulus, in order to maintain the body's centre of mass within manageable limits of the base of support or in transit to a new base of support (Rose 2005). After considering this fact total six exercises were chosen for the geriatric group. So this will not only challenge their centre of gravity but also stimulate lower limb muscles to complete the task.

Six exercises are taught to the person and after that each individual is asked to perform the same exercise to confirm that they have understood properly. Five exercises is as follows

1. *Heel to toe walking-2 minutes*
2. *One leg standing-up to maximum time or maximum 1 minute*
3. *Foreword lunges-10 repetition with 5 sec hold*
4. *Step up-10 repetition on both side with usual step height that is 12 to 14 inches*
5. *Mini squat ( holding with chair /table )-10 repetition*
6. *Standing with arm and heel raise -10 repetition with 5 sec hold*

*Each individual is asked to perform these exercise five times in a week for six weeks. After each week reminder was given to the participants regarding the continuation of the exercise programme by telephone. And after six weeks again BBS score was measured and compared with the previous score.*

### **3: OUTCOME:**

*Primary outcome was BBS. The score of BBS was taken before and after 6 weeks of training of physical exercise.*

### **4: STATISTICAL ANALYSIS:**

We have included those only who could complete the study for 6 weeks and remaining participants were excluded from the study.

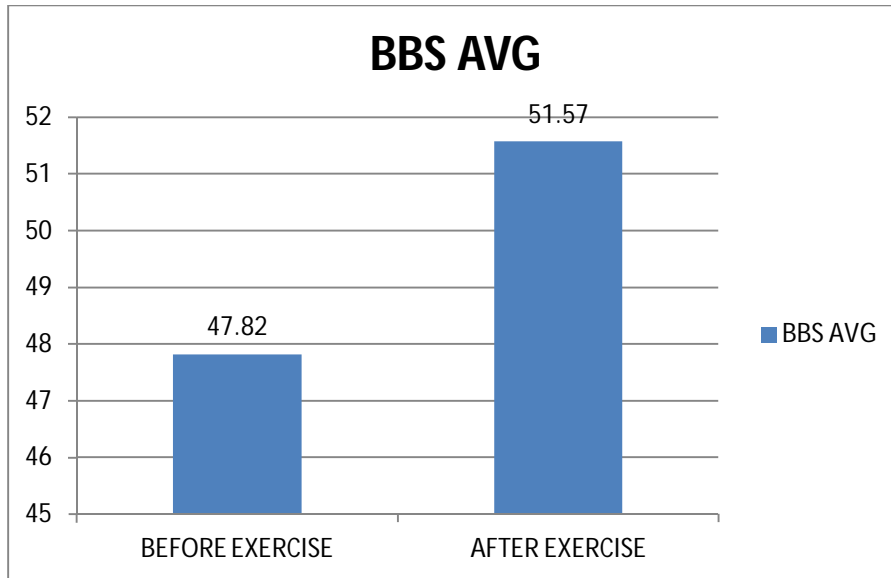
We used paired t test to compare the data between before and after the exercise.

All analysis was done on the simple excel format. Mean, SD and whether the score is significant or not was found out by simple excel formula.

### **5: RESULTS:**

We have included 47 participants in the study but 7 participants could not complete the study so we have excluded them from the study and the end of study the primary data was 40 participants. In the following chart the average score of BBS is mentioned before and after 6 weeks of training, same score is also shown in the chart also.

	BEFORE EXERCISE	AFTER EXERCISE
BBS AVG	47.82	51.57



The results showed that there is significant improvement in the score of BBS when it compared before and after the exercise. There was improvement in the BBS score in each participant.

## 6: DISCUSSION:

In our study exercise like forward lunges, one leg standing, step up and mini squat exercises includes strengthening of the quadriceps muscle and this can be the primary factor for the improvement in the score of BBS. Other exercise like standing on heel with arms flexed completely has stimulated calf muscle to work against gravity to complete the task. Calf muscle is anti gravity muscle and walking with the one foot just ahead and the heel of one foot is touched to the fingers of the other foot.

According to Alberta Vallejo et. al., strengthening exercise is an effective means to increase skeletal muscle strength in older persons even in to advanced age. Such improvements translated to enhanced skeletal muscle power which has been correlated with improved gait acceleration , stair climbing speed, improved get up and go times, and other functional measures (stair decent time, berg balance test) in older persons.<sup>27</sup> Binder et.al (2005) studied the effects of resistive training on 91 in community subjects with frailty syndrome (75 years and older) in a randomized controlled trial and concluded that in general significant ameliorations (up to >50% strength gain) can be expected even after 6 weeks of resistance training at a rhythm of 2-3 sessions per week.<sup>13</sup> This also supports our study.

Muscle weakness particularly of the lower limbs, is associated with reduced walking speed, increased risk of disability and falls in older people.<sup>16</sup> So strengthening of these muscle can improve balance.

## **7: LIMITATION OF THE STUDY:**

This study has included only 40 participants. We have included the participants whose score is more than 50, as BBS suggest that risk of fall is increased as the score is less than 36. So it cannot be concluded that same results would have come if participants score is less than 36.

## **8: CONCLUSION:**

In the old age group muscle weakness, joint stiffness, proprioceptive deficit is very common which leads to imbalance and ultimately increasing the risk for fall. Fall itself is very hazardous for the old age group as bone density will be reduced and can cause fracture of upper limb or lower limb bone. So it is highly advised that weight

bearing exercise like one leg standing, tandem walking as well as functional strengthening exercises like forward lunges, mini squatting and stepping exercises can be very helpful for the older individual which increases the balance and strength in the lower limb and reduces the chances of fall.

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**COMPARISON OF EPIDURAL BUTORPHANOL VERSUS FENTANYL WITH  
BUPIVACAINE FOR POST OPERATIVE ANALGESIA IN LOWER ABDOMINAL  
AND LOWER LIMB SURGERIES**

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## **ABSTRACT:**

**Background:** This prospective randomized controlled clinical comparative study entitled “COMPARISON OF EPIDURAL BUPIVACAINE AND BUTORPHANOL VERSUS EPIDURAL BUPIVACAINE AND FENTANYL FOR POST OPERATIVE ANALGESIA IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES” was conducted in 50 patients of either sex, aged between 18- 60 years of ASA grade I and II admitted for elective surgeries during 2011-2013.

**Material & Method:** Written informed consent was taken and pre-anesthetic evaluation was done. Epidural catheter was inserted and all patients were given spinal anesthesia using 0.5% hyperbaric Bupivacaine (15mg). In the postoperative period, when patient complained of pain, intensity of pain was assessed using Visual analog scale and when VAS score was 4 or more they received epidural Bupivacaine (0.5%) 2.5 ml and Butorphanol 2mg (group BB) or Bupivacaine (0.5%) 2.5 ml and Fentanyl 50µg (group BF) diluted to 10ml with NS. Parameters were observed were; Onset of analgesia; Duration of analgesia. ; Cardio- respiratory effects and adverse effects.

**Demographic profile** (age, sex weight hemodynamics and ASA grade) was comparable in both groups.

**Onset of analgesia:** Mean onset of analgesia was rapid (4.5+1.06S.D) minutes) in group BF when compared to group BB (6+1.32 (S.D) minutes. This was clinically and statistically significant ( $p < 0.001$ ).

**Duration of analgesia:** Duration of analgesia was longer in group BB which ranged from 300-550 minutes with a mean of 410+50.29 minutes compared to group BF which ranged from 250-450 minutes with a mean of 330+39.32 minutes. This was clinically and statistically significant ( $p < 0.001$ ).

**Cardio- respiratory effects:** There was no significant difference in heart rate, blood pressure and respiratory rate monitored at regular intervals for 12 hours postoperatively between the two study groups.

**Adverse effects:** Sedation was the main side effect in group BB. Frequency of pruritis and nausea-vomiting was more in group BF. Hypotension and respiratory depression were not found statistically significant in either group.

All patients were monitored for 12 hours postoperatively for any untoward effects.

## **Introduction:**

The International Association for the study of pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”.

Pain after surgery is inevitable. Postoperative pain causes stress and upsets most of the major organ functions. Hence, relieving pain is one of the fundamental responsibilities of anesthesiologists.

The epidural route is more popular for postoperative pain management as the technique can be used alone or in combination with general anaesthesia. Epidural technique has been found to provide better pain relief than systemic opioids and also decreased incidence of postoperative complications. Epidural administrations of opioids and local anesthetics have evolved in parallel with intrathecal techniques.

Among opioids, Morphine, Pethidine, Fentanyl, Sufentanyl, Buprenorphine and Butorphanol are most commonly used drugs epidurally. In the present study, Fentanyl and Butorphanol have been selected as an adjuvant to Bupivacaine for postoperative epidural analgesia.

### **Aims and objectives**

A comparison of epidural Bupivacaine and Butorphanol versus epidural Bupivacaine and Fentanyl for post operative analgesia focusing on Onset and duration of analgesia, Cardio respiratory effects, Sedation, Adverse effects.

### **MATERIAL AND METHOD**

Fifty adult patients of ASA grade I and II, of either sex, belonging to 18-60 years of age, posted for elective lower abdominal and lower limb surgeries in general surgery, orthopedics, gynecology, urology and plastic surgery were selected for the study. Patients were randomly divided into two groups of 25 each.

**GROUP BB-** Bupivacaine (0.125%) with Butorphanol (2mg)

**GROUP BF-** Bupivacaine (0.125%) with Fentanyl (50µg).

### **EXCLUSION CRITERIA:**

1. *Patients with cardio-respiratory disorders.*
2. *Patients with renal and / or hepatic disorders.*
3. *Contraindications for epidural anesthesia.*
4. *Patients physically dependent on narcotics.*
5. *Patients with history of drug allergy.*
6. *Head injury cases.*

### **PRE- ANESTHETIC EVALUATION:**

Patients were visited on the previous day of the surgery, a detailed clinical history was taken, and general and systemic examinations were done. Basic laboratory investigations ECG and chest x-ray were carried out routinely on all patients. The patients were explained about the spinal-epidural technique and VAS scale. A written informed consent was taken from each patient.

### **PREMEDICATION:**

To allay the anxiety and apprehension all patients were given Tablet Alprazolam (0.25mg) at 10pm in the night before the surgery. Patients were kept nil orally for 8 hrs before surgery.

### **ANESTHESIA:**

Epidural catheter was inserted for postoperative analgesia and all patients were operated under spinal anesthesia using hyperbaric Bupivacaine (0.5%) 3ml (15 mg).

### **ANESTHETIC TECHNIQUE:**

- *An intravenous line was secured with 18G cannula and Ringer lactate (R.L.) 1 litre infusion was started.*
- *Routine monitors like ECG, NIBP, Pulseoximetry were connected for every case and basal vital signs were recorded before starting the procedure*
- *Drugs and equipments necessary for resuscitation and general anesthesia administration were kept ready. An autoclaved spinal-epidural tray was used.*
- *Sterile disposable epidural set was used and checked for any manufacturing problems..*
- *Under all aseptic and antiseptic precautions The epidural space was identified using 18G disposable Tuohy needle with hanging drop technique at L2- L3 interspace. Then 20G PORTEX epidural catheter was passed through the epidural needle in upward direction till about 4cms of the catheter was in the space. The needle was withdrawn and the catheter was fixed to the back using adhesive tape. Then spinal anesthesia was given in the one interspace below the catheter with 23 G Quinke needle using hyperbaric Bupivacaine (0.5 %) 3ml.(15 mg)*
- *Intraoperatively level of sensory and motor blockade, blood loss, urine output and other routine monitors as described above were observed.*
- *No narcotics were administered during the intraoperative period.*
- *Fluid management: To begin with, R.L was infused and maintained with R.L, N.S or D.N.S. Blood was transfused only when indicated.*

### **POST OPERATIVE PERIOD:**

After completion of the surgery, patient was shifted to recovery room and monitoring was continued. When patient recovered from motor blockade, they were shifted to postoperative ward.

In the postoperative period, when the patient first complained of pain, intensity of pain was assessed using VAS scale. When the VAS score was 4 or more, **study drug** was given through epidural catheter after confirming its proper position as:

**GROUP BB-** received Bupivacaine (0.5%) 2.5 ml and Butorphanol 2mg diluted to 10ml in NS.

**GROUP BF-** received Bupivacaine (0.5%) 2.5 ml and Fentanyl 50µg diluted to 10 ml in NS.

The intensity of pain and pain relief was assessed using VAS at 5, 10,15,30,60 minutes 2hours, and thereafter 2 hourly for12 hours postoperatively. As and when the patient complains of further pain during the period of observation, intensity of pain was assessed again using VAS to know the effect of the study drug given earlier. If it was 4 or more, rescue analgesia was given in form of Injection Diclofenac 75 mg intravenously slowly as per the ward protocol and the study would end at this stage.

### **VISUAL ANALOG SCALE SCORE**

Visual analog scale (VAS) consisted of a 10 cm line, marked at 1cm each on which the patient makes a mark on the line that represents the intensity of pain he/she was experiencing. Mark '0' represents no pain and mark '10' represents worst possible pain. The numbers marked by the patient was taken as units of pain intensity.

### **OBSERVATIONS:**

1. *Onset of analgesia.*
2. *Duration of analgesia.*
3. *Cardio- respiratory effects: Heart rate, blood pressure and respiratory rate.*
4. *Adverse effects like sedation, pruritis, nausea, vomiting, respiratory depression and hypotension. Urinary retention could not be studied, as most patients in the study had indwelling urinary catheter inserted as part of the surgical management.*

**Onset of analgesia:** is the time interval from administration of the study drug (VAS score of 4 or more) to first reduction in pain intensity by at least 10 mm in VAS.

**Duration of analgesia:** is the time interval between onset of analgesia, till patient complaints of pain (VAS score 4 or more) when rescue medication was given.

**Sedation** - Quality of sedation after giving the study drug was based on ramsay sedation assessment scale.

**Hypotension** - A fall of 30 % in BP from baseline value.

**Respiratory depression** – A respiratory rate of less than 10 breaths/ min

**Bradycardia** - A fall of 20% in pulse rate from base line value.

### **MANAGEMENT OF ADVERSE EFFECTS**

**Hypotension:** IV fluids and Injection Ephedrine 6 mg SOS.

**Bradycardia:** Injection Glycopyrolate 0.2 mg IV.

**Respiratory depression and deep sedation:** Supportive measures like Stimulation, Oxygen with nasal prongs and IV Naloxone 0.4 to 2 mg SOS.

**Nausea-vomiting:** Injection Ondansetron 4 mg IV.

**STATISTICAL METHODS**<sup>5</sup>:.. Student t test (two tailed, independent) has been used to find the significance of duration of analgesia, onset of analgesia and VAS scores between two groups, Chi-square and Fisher Exact test has been used to find the significance incidence of side effects between two groups. Microsoft word and Excel have been used to generate graphs, tables etc.

## OBSERVATION AND RESULTS

Fifty adult patients belonging to ASA grade I and II, of either sex, in age group between 18- 60 years, posted for elective lower abdominal and lower limb surgeries under spinal anaesthesia were selected for the study. They were randomly allocated to two groups with 25 patients in each group. In **Group BB**- Bupivacaine (0.125%) + Butorphanol (2 mg) were used as the study drug and in **Group BF**- Bupivacaine (0.125%) + Fentanyl (50µg) were used as the study drug for the relief of postoperative pain. This comparative clinical study was undertaken to study the efficacy based on onset of analgesia, duration of analgesia and adverse effects.

### DEMOGRAPHIC DATA:

VARIABLES	GROUP BB	GROUP BF
AGE (MEAN+SD)	39+11.58	40+11.63
SEX RATIO (M:F)	12:13	12:13
WEIGHTMEAN+SD)	67+6.04	68+5.58
PULSE(MEAN+SD)	77+8.13	77+8.11
SBP(MEAN+SD)	123+9.42	122+10.01
DBP(MEAN+SD)	75+7.47	75+6.48
RR(MEAN+SD)	14+1.41	14+1.45
ASA GRADE(I:II)	19:6	19:6

Both group were also comparable with respect of sex distribution, weight, haemodynamics and ASA GRADE ( $p>0.05$ ).

**ONSET OF ANALGESIA:**

ONSET OF ANALGESIA(MIN)	GROUP BB	GROUP BF
2-4	3	13
4-6	15	10
6-8	6	2
>8	1	0
<b>MEAN ±SD</b>	6±1.32	4.5±1.06

60% of the patients in group BB had onset of analgesia between 4-6 minutes and 24% between 6-8 minutes. In group BF, 52% of patients had onset of analgesia between 2-4 minutes and 40% of patients had onset between 4-6 minutes.

Statistical analysis showed that onset of analgesia in group BB was delayed and statistically strongly significant with  $t=4.43$  and  $p < 0.001$ .

**DURATION OF ANALGESIA:**

DURATION OF ANALGESIA(MIN)	GROUP BB	GROUP BF
250-300	0	5
300-350	4	14
350-400	5	4
400-450	12	2
450-500	3	0
500-550	1	0
<b>MEAN+ SD</b>	410±50.29	330±39.32

Statistical analysis showed that duration of analgesia was less in group BF and statistically strongly

significant with  $t=6.26$  ( $p < 0.001$ ).

**CARDIOVASCULAR AND RESPIRATORY EFFECTS:**

There was no differences with regard to pulse rate and blood pressure (both systolic and diastolic) between the two groups observed ( $p > 0.05$ ). It can also be noted that the difference in respiratory rate was not statistically significant ( $p > 0.05$ ) in both the groups.

#### ADVERSE EFFECTS:

ADVERSE EFFECTS	GROUP BB		GROUP BF	
	no	%	no	%
SEDATION	9	36	3	12
PRURITIS	0	0	4	16
NAUSEA-VOMITING	2	8	7	28
RESPIRATORY DEPRESSION	0	0	2	8
HYPOTENSION	0	0	1	4

From the above chart it can be observed:

**Sedation** was observed in 9 patients (45%) of group BB and 3(12%) patients of group BF. This was statistically strongly significant ( $p < 0.001$ ).

**Pruritis** was seen 4 patients (16%) of group BF and in none of the patients of group BB which was statistically significant ( $p < 0.05$ ).

**Nausea and Vomiting** were observed in 2 patients (8%) in group BB and in 7 patients (28%) in group BF which was statistically significant ( $p < 0.05$ ).

**Respiratory depression** was seen in only 2 patients (8%) and **Hypotension** in only 1 patient (4%) of group BF and in none of the patients of group BB. These were statistically insignificant ( $p > 0.05$ ).

#### SEDATION SCORE:

Sedation was observed in 9 patients (36%) in group BB whereas 3 patients (12%) in group BF had sedation which was statistically significant ( $p < 0.001$ ). The quality of sedation was acceptable in the interest of patients well being.

#### Discussion:

The present study is a prospective randomized controlled clinical comparative study done to assess the efficacy and safety of epidural Bupivacaine and Butorphanol

versus epidural Bupivacaine and Fentanyl for the management of postoperative pain in lower abdominal and lower limb surgeries. A total of 50 patients belonging to age groups 18-60 years of ASA grade I-II have been taken. Male and female patient ratio was equal. Patients undergoing elective lower abdominal and lower limb surgeries in general surgery, orthopedics, gynecology, urology and plastic surgery were selected. During the preoperative assessment patients were explained about the epidural procedure and VAS score. Pre-medication Tablet Alprazolam 0.25mg orally was given the night before the surgery.

Patients were randomly divided into two groups of 25 each, Group BB – Bupivacaine and Butorphanol and Group BF – Bupivacaine and Fentanyl. Epidural catheter was inserted and all patients were given spinal anaesthesia. In the postoperative period, when patient complained of pain, intensity of pain was assessed using VAS and when VAS score was 4 or more, patients in group BB received epidural Bupivacaine 0.5% 2.5 ml and Butorphanol 2mg diluted to 10ml NS and patients in group BF received epidural Bupivacaine 0.5% 2.5 ml and Fentanyl 50µg diluted to 10ml in NS. Observations recorded are Onset of analgesia, Duration of analgesia, Cardio-respiratory effects and adverse effects.

#### **ONSET OF ANALGESIA:**

In our study, the mean time for onset of analgesia in group BB was  $6 \pm 1.32$ (SD) minutes and in group BF was  $4.5 \pm 1.06$  (SD) minutes. Majority of patients in group A had onset of analgesia between 4-6 minutes whereas in group BF between 2-4 minutes. Statistical analysis showed that onset of analgesia was delayed in group BB compared to group B ( $t=4.43$ ;  $p < 0.001$ ).

We can correlate our study with the studies conducted by:

**Mok et al,<sup>15</sup> in 1986** did a study to evaluate the analgesic efficacy and safety of epidural Butorphanol 4mg in comparison to that of epidural morphine 5mg in patients with postoperative pain. Onset of pain relief with epidural Butorphanol appeared at 15 minutes.

**Rutter DV et al<sup>12</sup>, in 1981** reported that 100µg of epidural Fentanyl for postoperative pain relief had a rapid onset of action i.e. almost 50% reduction in mean pain within 5 minutes.

**Aswini A. et al<sup>3</sup>, in 2009** conducted a comparative study of epidural Butorphanol 4mg and epidural Fentanyl 100 µg for the relief of postoperative pain in lower abdominal and lower limb surgeries. The onset of analgesia was clinically and statistically significantly late (6minutes) in Butorphanol group when compared to Fentanyl group (3minutes).

#### **DURATION OF ANALGESIA:**

In the present study, duration of analgesia in group A ranged from 300-550 minutes(5 - 9 hrs) with a mean  $\pm$  S.D of  $410 \pm 50.29$  min and in group B ranged from 250-450 minutes(4 - 7.5 hours) with a mean  $\pm$  S.D of  $330 \pm 39.32$  min. The statistical analysis showed that duration of analgesia in group A was significantly longer when compared to group B ( $t=6.26$ ;  $p < 0.001$ ).



Our study is in agreement with the studies conducted by:

**Mok et al, in 1986<sup>15</sup>** concluded that duration of analgesia with Butorphanol 4mg averaged 5.4 hrs.

**Shivakumar T. C. et al<sup>13</sup>, in 2006** evaluated analgesic efficacy and side effects of 2 doses of epidural Butorphanol in lower abdominal surgeries. Patients were randomly assigned to three groups to receive epidural Bupivacaine 0.5% 16 ml (n=25 control group I), Bupivacaine 0.5% 15 ml + 1 ml 2 mg Butorphanol (n=25, group II) and Bupivacaine 0.5% 14 ml + 2 ml of 4 mg Butorphanol (n=25, group III). Maximum patients demanded rescue analgesics in Group I (36%) and Group II (32%) at 7<sup>th</sup> hour and in group III (40%) at 9<sup>th</sup> hour.

**Neerja Bharti et al<sup>8</sup>, in 2009** The duration of analgesia was prolonged in patients receiving Butorphanol (2 mg, 4 mg) with Bupivacaine (0.125%) combination ( $8.68 \pm 0.82$  hrs,  $9.82 \pm 0.54$  hrs) as compared with Butorphanol alone ( $4.35 \pm 0.66$  hrs;  $P < 0.05$ ).

**Aswini A. et al<sup>3</sup>, in 2009** Duration of analgesia was clinically and statistically longer in Butorphanol group (350 minutes) in comparison to Fentanyl group (230 minutes).

#### **CARDIOVASCULAR AND RESPIRATORY EFFECTS:**

In the present study heart rate, blood pressure and respiratory rate remained stable throughout the observatory period. 1 patients in group BF had hypotension (fall in systolic BP <20% of basal reading) and 2 patients in group BF had respiratory depression (RR<10/min) which was not statistically significant ( $p > 0.05$ ). Our study can be compared to the following studies:

**Premila Malik, Chhavi Manchanda, Naveen Malhotra<sup>9</sup>**in Their study showed that there were no significant changes in pulse rate, systolic and diastolic BP, RR and SpO<sub>2</sub> in the 2 groups at different time intervals throughout the 24 hours study period ( $p > 0.05$ ).

**Aswini A. et al<sup>3</sup>, in 2009** There were no significant changes in pulse rate, BP and RR in either group throughout post operative period.

**ADVERSE EFFECTS:** In our study;

**Sedation:** It was the main side effect in Bupivacaine and Butorphanol group which constituted 45% compared to Bupivacaine and Fentanyl group (12%). Majority of the patients had mild sedation, patient sedated but arousable. This was statistically significant.

**Catherine O Hunt<sup>7</sup>** in his study has reported a higher incidence of sedation with epidural Butorphanol and is a dose dependent side effect.

**Pruritis:** In our study none of the patients in group BB had pruritis and 4 patients (16%) in group BF had pruritis which was statistically significant ( $p < 0.05$ ).

**Premila Malik, Chhavi Manchanda, Naveen Malhotra<sup>9</sup> 2006** shows that pruritis was higher in epidural fentanyl group ( $p < 0.05$ ).

**Nausea and vomiting:** In our study 2 patient in group BB had nausea-vomiting whereas in group BF 7 patients had nausea-vomiting which was significant statistically ( $p < 0.05$ ).

No patients on epidural Butorphanol had nausea or vomiting in study conducted By **Catheline O Hunt et al<sup>7</sup>**.

**Premila Malik, Chhavi Manchanda, Naveen Malhotra<sup>9</sup> in 2006** shows that the incidence of nausea and vomiting was higher in Fentanyl group.

**Respiratory depression and Hypotension:** In our current study, in group BF 2 patients had respiratory depression and 1 patient had hypotension and in none of the patients in group BB had hypotension or respiratory depression which were not significant ( $p > 0.05$ ).

No patients had respiratory depression or hypotension with Butorphanol in studies conducted by **Catherine O Hunt et al in 1989<sup>7</sup>**.

### **Conclusion:**

It can be concluded from the above study that Butorphanol 2 mg administered epidurally in comparison to Fentanyl 50 $\mu$ g (along with 0.125% Bupivacaine) is safe and effective in providing good pain relief of moderate duration in the postoperative period and is associated with only minimal adverse effects.

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## **7 EFFECT OF TIMING OF ONDANSETRON ADMINISTRATION ON ITS EFFICACY AS A PROPHYLACTIC ANTIEMETIC IN PATIENTS UNDERGOING GYNECOLOGICAL LAPAROSCOPIC PROCEDURES**

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### **Abstract:**

**INTRODUCTION** : Although ondansetron (4 mg IV) is effective in the prevention and treatment of postoperative nausea and vomiting (PONV) after gynecological laparoscopic surgery, the optimal timing of its administration, and the effect on the patient's quality of life after discharge have not been established.

**METHOD:** In this placebo-controlled study, 90 healthy women undergoing gynecological laparoscopic procedures were randomized to receive placebo (Group A), ondansetron 4 mg before induction (Group B), and ondansetron 4 mg at the end of surgery (Group C).

**RESULTS:** Compared with placebo and ondansetron given before induction of anesthesia, ondansetron administered after surgery was associated with lower nausea, decrease incidence of emesis (more than two episodes), earlier intake of normal fluid and food during first 24 hours post operatively. This prophylactic regimen was also associated with highest patient satisfaction.

**CONCLUSION:** Compared with placebo and ondansetron given before induction of anesthesia, ondansetron administered after surgery significantly reduced the incidence of PONV in the post anesthesia care unit and during the 24-h follow-up period, it also facilitated the recovery process by reducing the time to oral intake for fluid and a normal diet. It also improves patient's quality of life after surgery.

**Key Words:** Ondansetron, Antiemetic, Gynecological Laparoscopic Surgery.

**“THE EFFECT OF TIMING OF ONDANSETRON ADMINISTRATION ON ITS EFFICACY AS A PROPHYLACTIC ANTIEMETIC IN PATIENTS UNDERGOING GYNECOLOGICAL LAPAROSCOPIC PROCEDURES”**

**INTRODUCTION:** In laparoscopic procedure, the peritoneal cavity is inflated with carbon dioxide, that triggers vagal afferents on the bowel and peritoneum, which induces emesis by activating the vomiting center. This insufflations also leads to abdominal discomfort, if abdominal cavity is not adequately decompressed after the procedure, further adding to general level of unpleasant sensations(1). Pain, Nausea (subjectively unpleasant sensation associated with awareness of the urge to vomit), vomiting (forceful expulsion of gastric contents from the mouth) and retching (labored, spasmodic, rhythmic contraction of the respiratory muscles without the expulsion of gastric contents) are frequently listed by patients as their most important peri operative concerns(1). Women undergoing gynecological surgery are particularly at risk of experiencing these problems. Obesity appears to increase the risk of PONV because fat soluble anesthetic agents may accumulate in adipose tissue which then release and slowly causing postoperative emesis. Female patients have 3 times greater incidence of emetic symptoms than males, due to increased gonadotropin, estrogen, and plasma progesterone levels during their menstrual cycles(1).

Drugs known to block dopamine, histamine and muscarinic cholinergic receptor have antiemetic effects (2). A wide variety of prophylactic antiemetic, including antihistamines(e.g., hydroxyzine, promethazine), butyrophenones (e.g., droperidol), and gastro kinetic agents (e.g., metoclopramide), have been successfully used to reduce the

incidence of postoperative nausea and vomiting (PONV) in the ambulatory setting, but some of these older antiemetic may be associated with undesirable side effects. Ondansetron, a 5-HT<sub>3</sub> receptor antagonist, is effective for both the prevention and treatment of PONV without producing significant side effects. The most frequently reported side effects of ondansetron include constipation and headache (3). The site of action of ondansetron is thought to be 5-HT<sub>3</sub> receptor located in the visceral afferent vagus and area postrema. Ondansetron administered before induction of anesthesia is based on the hypothesis that blockade of receptors in the chemoreceptor trigger zone before the arrival of emetic stimuli associated with anesthesia and surgery provides greater antiemetic efficacy(4).

**AIMS:** Ondansetron (4 mg IV) is effective in the prevention and treatment of postoperative nausea and vomiting. The aim of this study is to find out the **effect of timing of ondansetron administration** for (i) Efficacy of drug and (ii) Incidence of PONV (iii) its effect on patient's quality of life after surgery.

**MATERIAL AND METHOD:** The present study was conducted in 90 patients of ASA I/II, aged 20-60 years, scheduled for elective gynecological laparoscopic surgeries after taking written informed consent. Exclusion criteria: Patients with pregnancy, breastfeeding, renal or liver disease, psychological illness, history of alcoholism or opioid addiction, consumption of antiemetic drug 3 days preceding the intervention, occurrence of nausea or vomiting in the same period and conditions associated with delayed gastric emptying such as gastrointestinal obstruction, pyloric stenosis, chronic cholecystitis, diabetes mellitus and neuromuscular disorders were excluded from the study. All routine investigations were assessed preoperatively and patients were kept nil by mouth for 8 hours. On arrival in the operating room routine monitoring devices were applied and baseline blood pressure, heart rate, pulse oximetry values were recorded.

**Premedication:** Inj. Glycopyrrolate 0.2 mg IV and Inj. Fentanyl 1.5-2 microgram/kg IV .

Group A (Placebo): saline,

Group B: Ondansetron 4 mg 2-3 mins before induction,

Group C: Ondansetron 4 mg at the end of surgery

(30 patients in each group).

**Induction:** inj. Pentothal 3-5 mg/kg IV and inj.succinylcholine 1.5-2 mg/kg IV.

Intubation done with appropriate sized cuffed endotracheal tube. Anesthesia was maintained with oxygen, nitrous oxide (N<sub>2</sub>O) and sevoflurane (2-3%). Inj. Atracurium 0.5 mg/kg IV given when required. Patients were reversed with inj. Neostigmine 0.05 mg/kg IV and inj. Glycopyrrolate 0.4 mg IV. Tracheal extubation done after proper suctioning. Then patients were transferred to post anesthesia care unit (PACU).

**PACU:** In the PACU all vitals were monitored. Incidence of PONV noted on admission and 1 hour after that. Metoclopramide 10-20 mg IV was given as the rescue antiemetic if the patient experienced repeated (two or more) episodes of emesis or sustained

nausea lasting 15 mins. Assessment of quality of life was done by first fluid intake and resumption of normal food & oral food intake. Level of satisfaction also noted.

**Statistical analysis:** performed with ANOVA test for continuous variables expressed as mean  $\pm$  SD (patient's age, weight). Discrete variables, such as the incidence of nausea, vomiting and first oral intake, resumption of normal food and degree of satisfaction, were compared by using chi square, Fisher's exact tests. P value of 0.05 was considered significant.

## OBSERVATIONS AND RESULTS

**Table 1: Demographic Data**

GROUPS	A	B	C
AGE (year)	39 + 7	39 + 9	38 + 9
WEIGHT(kg)	61 + 11	61 + 9	63 + 12
ASA I / II	24 / 6	22 / 8	25 / 5

**Table 2: Incidence of PONV**

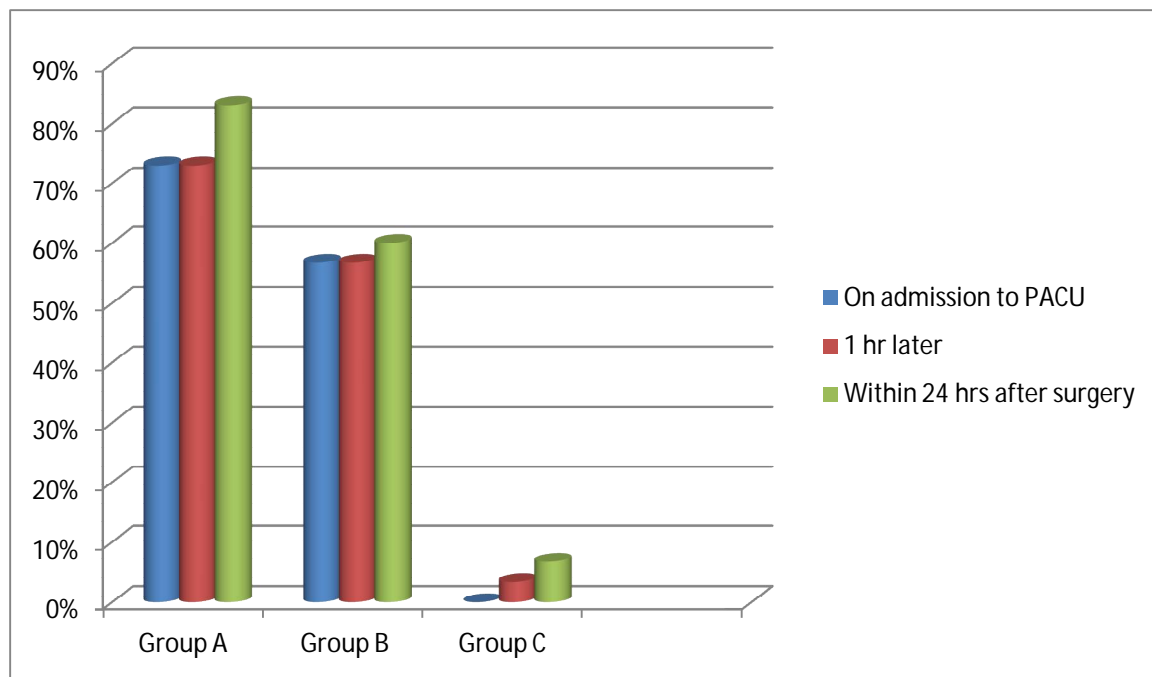
GROUPS	A	B	C	P Value	
				A & C	B & C
<b>NAUSEA</b>					
On admission to PACU	22(73%)	17(56.66%)	0(0%)	<0.001	<0.001
1 hr later	22(73%)	17(56.66%)	1(3.33%)	<0.001	<0.001
Within 24 hr after surgery	25(83%)	18(60%)	2(6.66%)	<0.001	<0.001
<b>VOMITING</b>					
On admission to PACU	18(60%)	10(33.33%)	0(0%)	<0.001	<0.001
1 hr later	18(33.33%)	11(36.66%)	1(3.33%)	<0.001	<0.005
Within 24 hr after surgery	20(66.66%)	13(43.33%)	1(3.33%)	<0.001	<0.001
<b>RESCUE antiemetic in PACU</b>	25(83%)	22(73%)	3(10%)	<0.001	<0.001

**Table 3: Assessment of Quality of Life**

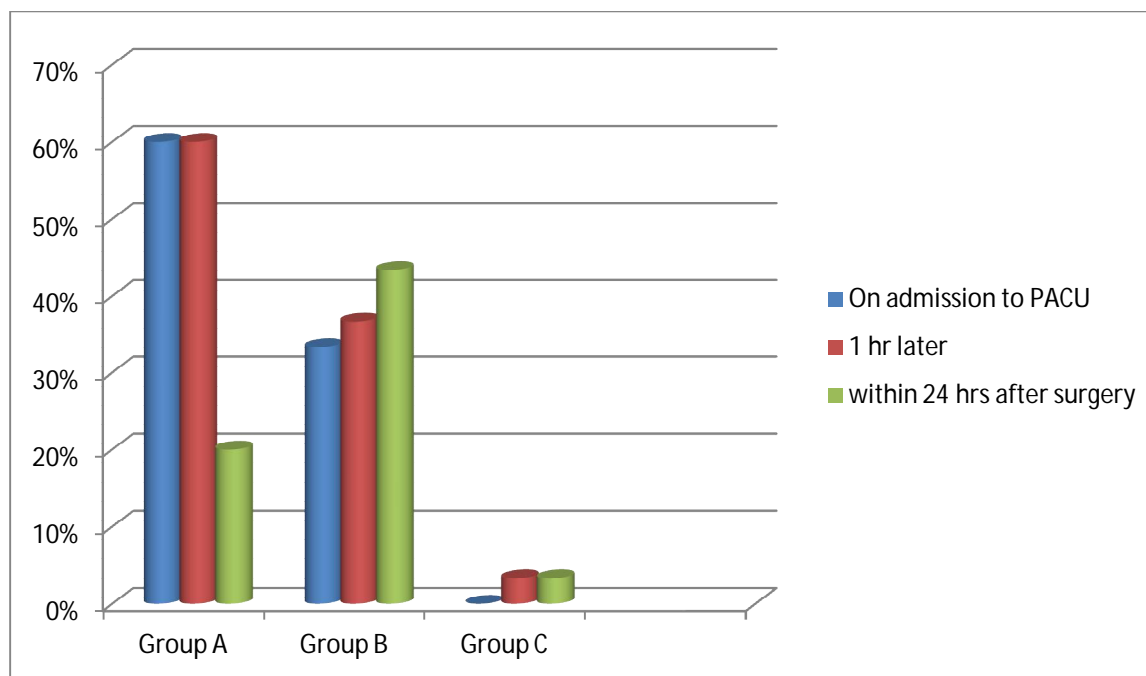
GROUPS	A	B	C	P value	
				A & C	B & C
Resumption of oral fluids : Day of surgery	19(63.33%)	20(66.66%)	27(90%)	<0.025	<0.05

1	9(30%)	7(23.33%)	2(6.66%)	<0.025	<b>&lt;0.75</b>
day after surgery					
Resumption of normal food : Day of surgery	10(33.33%)	12(40%)	20(67%)	<0.01	<0.05
1	13(43.33%)	8(26.66%)	5(16.6%)	<b>&lt;0.75</b>	<b>&lt;0.25</b>
day after surgery					
Degree of satisfaction : Highly satisfied	10(33.33%)	18(60%)	25(83.33%)	<0.001	<0.05
Satisfied	6(20%)	6(20%)	5(16.6%)	<0.001	<0.01

**Chart 1: Incidence of Nausea**



**Chart 2: Incidence of vomiting**



There was no significant difference in demographic characteristics between all three groups as shown in table 1. In the PACU, patients in Group B & Group C experienced less nausea compared with Group A, whereas the incidence of vomiting was significantly decreased in Group C (Table-2; p values statistically significant). However, the times to resumption of regular fluids and normal food were significantly decreased in Group C (Table 3; p values statistically significant) compared with other two groups. Patient satisfaction also differed significantly among the three groups, with more patients being highly satisfied in the Group C (Table 3; p values statistically significant). There were no significant differences in the incidence of nonemetic postoperative side effects among all three groups. There were also no significant differences in the times to eye opening, tracheal extubation, response to verbal commands, and orientation among the three groups.

**DISCUSSION:** Ondansetron, a 5-HT<sub>3</sub> receptor antagonist, is highly effective in preventing and treating nausea and vomiting. However, in most of the studies evaluating the prophylactic antiemetic efficacy of ondansetron, the drug was administered immediately before the induction of anesthesia. Only one published study has reported that ondansetron was effective in preventing PONV when administered after surgery (5). Ondansetron has a relatively short elimination half-life of  $2.8 \pm 0.6$  hours, it seemed logical that it might be more effective when administered after surgery, thereby producing a more sustained antiemetic effect in the postoperative period (6). The choice of a 4-mg ondansetron dose was based on pooled data from studies that suggested this was the optimal dose for the prophylaxis of PONV. Its lack of side effects has made ondansetron popular in ambulatory surgery (7). The administration of ondansetron at the end of surgery was associated with shorter times to - first oral intake, resumption of the normal meals on the day of surgery, lower PONV. Patient satisfaction was significantly higher in ondansetron treatment groups than in the



placebo group. The incidence of nausea was higher than the incidence of vomiting in this study because some patients developed severe nausea without vomiting, whereas all of the patients experiencing emesis were also nauseated.

**Jun Tang, Baoguo Wang, Paul F. White**,<sup>(4)</sup> suggested that ondansetron 4 mg IV administered at the end of surgery is more effective in preventing PONV in the PACU, as well as in the post discharge period, than ondansetron administered as a split dose at the induction and the end of surgery. **Philip B, McLeskey C, Chelly J, et al.**<sup>(8)</sup> noted that dolasetron (another 5-HT<sub>3</sub> antagonist) 12.5 mg IV given 15 min before the end of the anesthetic was as effective in the prophylaxis of PONV as 25-, 50-, and 100-mg doses. There are few direct comparisons of the effect of timing of other antiemetics on their efficacy. **Enrico Polati, Giuseppe Verlato, Gabriele Finco et al.**<sup>(2)</sup> noted that ondansetron 4 mg IV has a greater efficacy/safety ratio than metoclopramide 10 mg IV when used to treat established PONV. **Klockgether- Radke et al.**<sup>(9)</sup> suggested that the timing of the administration of droperidol has no influence on postoperative emesis. However, **Kraus et al.**<sup>(10)</sup> reported that droperidol was more effective for prophylaxis against postoperative emesis when administered preoperatively. **Ferrari and Donlon** <sup>(11)</sup> determined that metoclopramide 0.15 mg/kg given on arrival in the PACU is an effective antiemetic in children undergoing tonsillectomy procedures.

**CONCLUSION:** Ondansetron 4 mg IV administered at the end of surgery is more effective in preventing PONV in the PACU, as well as in the post discharge period, than ondansetron administered before the induction of anesthesia. When ondansetron is administered at the end of surgery, it allows early resumption of fluids and normal food and improves the patient's quality of life after surgery.

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## **8 EVALUATION OF BIOLOGICAL REFERENCE INTERVAL OF 25 HYDROXY VITAMIN D IN WEST BENGAL**

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### **Abstract**

#### **Background**

The number of patients visiting pain clinic and being suggested for estimation of 25 hydroxy vitamin D(25OHD) have increased surprisingly. The 25OHD results being estimated by the laboratory have also shown values below the health reference range in majority number of cases. Such a large number of 25OHD deficient patient in adult population without any presentation of classical deficiency symptom except generalized pain and fatigue seems improbable and the author decided to evaluate the local health reference range. The manufacturer also suggests to evaluate the BRI in the laboratory in the inserts. The established Biological reference Interval (BRI) of 25 hydroxy Vitamin D(25OHD) which is popularly known as health reference range and BRI obtained from population based study by the kit manufacturer (Roche Diagnostics) were found out to be not in accordance. The local population results did not correlate with established BRI but nicely correlated with the population study result of the manufacturer.

#### **Method**

Healthy volunteers, male and female were chosen. Selection of healthy population was as per CLSI (Clinical & Laboratory Standards Institute) instruction. Reference range has been established from non parametric distribution. Both male and female patient

population were simultaneously evaluated to find out whether 25OHD was the sole attributor of the patient complaints or health reference range should be replaced by population based reference range. Patients are of same age group with the volunteers with no history of addiction and any other history of chronic disease or medication except they are from pain clinic came with the history of joint pain, body ache, fatigue. 25OHD of both patient and healthy volunteer group was estimated in Cobas e 411 system by electrochemiluminescence immunoassay (ECLIA). The pain profile parameters were uric acid (UA), total calcium (Ca), C-Reactive protein (CRP) and rheumatoid arthritis factor (RF) were usual test requirements along with 25OHD. The parameters were tested for both patient and volunteer group. The tests were performed in Cobas Integra 400 plus. Number of male healthy volunteers was 120 and female 122 which satisfies the criteria of CLSI for reference range determination.

### **Conclusion**

The BRI established by the laboratory is in accordance with the population study of Roche Diagnostics. The author mentions the evaluated reference range as "Laboratory Evaluated Reference range" in the test results.

### **Key words:**

**BRI (Biological Reference Interval), 25OHD, Percentile (p), Parametric distribution, Non parametric distribution**

### **AAAA Abbreviations**

1. UA
2. Ca
3. CRP
4. RF
5. BRI (Biological Reference Interval)
6. 25 Hydroxy Vitamin D (25OHD)

### **Introduction**

25 Hydroxy Vitamin D (25OHD) is presently being considered as a popular health check up parameter. As India is a tropical country insufficient exposure to sunlight is supposed to be very uncommon. But in practice, the accumulated patient data when assessed at random, showed a major population in West Bengal is suffering from 25OHD deficiency. There might be three possibilities:

1. *Present day life style i.e., lack of exposure to sunlight, use of Sun blockers having direct effect on 25OHD concentration.*
2. *Estimation of 25OHD was not popular earlier. So, either there was lack of awareness regarding 25OHD deficiency or evaluation of reference range is necessary.*

3. *In the manufacturers insert(Roche Diagnostics), though Biological Reference Interval(BRI) was stated to be  $\geq 30\text{ng/ml}$ , the range of consensus value for male and female population studied in North Germany reflected a different feature[1]. The patient population value obtained from the data collected from the laboratory resources of present author correlated well with the consensus range. The difference led to the need of evaluation of BRI.*

Extensive studies were made on prevention of Vitamin D deficiency. It was observed that exposure to sunlight and a diet rich in oily fish prevents Vitamin D deficiency[2-4]. The people living near to the equator who are exposed to sunlight without sun protection were stated to have robust level of 25OHD above 30 ng/ml. But in the sunniest areas like Saudi Arabia, United Arab Emirates, Turkey, India and Lebanon adults and children are having 25OHD levels  $<20\text{ng/ml}$  as most of the skins are shielded from the Sun[5,6]. In India a major population is not shielded from Sunlight neither user of Sun blockers. Hence, lack of exposure to sunlight may be ruled out for general population except a fraction of society having different life style as mentioned above. Moreover, the population of West Bengal are accustomed to have milk and oily fish in the diet and though 25OHD  $<20\text{ng/ml}$  have been defined by most experts as deficiency level no consensus on optimal level were obtained except by Roche Global which is only a study of a fraction of North German population and a study by Bischoff et al [7] recommending optimal concentration of 25OHD 36-40ng/ml and supplementation limit up to 600IU [1, 8]. Unfortunately, there are some studies which were unable to show any positive outcome of 25OHD supplementation [8]. A meta-analysis of seven randomized clinical trials that evaluated the risk of fracture in older persons given 400IU of Vitamin D<sub>3</sub> per day revealed little benefit with respect to the risk of either non-vertebral or hip fracture. In studies using doses of 700-800IU of Vitamin D<sub>3</sub> per day, the relative risk of non vertebral fracture was reduced by 23% and hip fracture by 26% as compared with calcium or placebo[8]. A Women's health initiative study that compared the effects of 400IU of Vitamin D<sub>3</sub> plus 1000mg of calcium per day with placebo in more than 36,000 postmenopausal women confirmed these results and reported an increased risk of kidney stones but no benefit with respect to the risk of hip fracture[8]. Hence, the outcome of such studies raises the question to what extent and to whom Vitamin D supplementation is necessary? Vitamin D being fat soluble vitamin may create toxicity situation if it is not being utilized. So, the question is whether Vitamin D supplementation needs to be done on the basis of health reference range or BRI needs to be redefined.

Several studies have been done showing direct relation of muscle weakness and 25OHD deficiency [6], control of Vitamin D on more than 200 genes [9, 10], link of Vitamin D deficiency with schizophrenia and depression [11]. The dilemma of whom to be declared as deficient yet remained inconclusive. Neither it is easy to accept that 95% population of a State of India are 25OHD deficient and remained undetected for

such a long time. Hence, it was felt that a group of volunteers would be selected and their concentration of 25OHD in serum would be estimated. Patient population data and healthy volunteer group data would be compared. Ideally, such study should be interstate and all over India but the author has only access to the local population. On the basis of accumulated data the author may mention the evaluated range as “laboratory defined range” in the test report along with textbook health reference range. But the author found out the reference range has been modified on the year 2008[1] and being implemented as BRI strengthening present study reports’

## **Materials and Methods**

### **Selection of healthy volunteers**

Adult healthy male and female volunteers were chosen. Age limit 25 – 60 years. As per Clinical and Laboratory Standards Institute (CLSI) guideline for BRI determination minimum number of volunteers should be 120[10]. In the present study 122 female and 120 male volunteers opted for the study. The volunteers were detailed about the project and they have given consent to give their blood sample for the study. The volunteers were having no previous history of addiction, no history of chronic illness, use of any medicine prior 6 months of the study. Neither male nor female volunteers were user of sun blockers. The minimum exposure to sunlight is at least 2 hours in the midday. The volunteers were having no history of backache, joints pain, fatigue, general weakness.

### **Selection of patients**

Age group and history of addiction is same as healthy population. The patient population have shown history of joint pain, backache, general weakness, body ache and diminished energy. Out of 1000 data 120 male and 143 female patient data were selected on the basis of age group & similarity in nature of complaint. The patients were not supplemented Vitamin D prior estimation. Though the patients had history of body ache, joint pain and diminished energy the pain parameters like RF, Ca, UA, CRP were within normal reference range. The clinician never mentioned the patients as case of rheumatoid arthritis (RF were normal), lupus or fibromyalgia. Neither they were suggested to test the Bone Mineral Density (BMD). The patients were suggested to supplement 25OHD on the basis of low 25OHD value as per health reference range ( $\geq 30$  ng/ml).

### **Methods**

The tests performed were 25OHD, Uric acid (UA), Total Calcium (Ca), C-Reactive Protein (CRP) and Rheumatoid Factor (RF). For the patient group the tests were suggested by the Clinician of Pain Clinic as the tests are in the standard pain clinic profile. For healthy volunteers also similar profile of tests were performed. 25OHD was estimated by electro-chemiluminescence immunoassay (ECLIA) in Cobas e 411 system. UA, Ca were estimated by Cobas Integra 400 plus system. CRP & RF were

estimated in EC-5 batch analyser by Immuno turbidimetric method. Internal quality control results were satisfactory. UA estimated by uricase method and Ca by OrthoCresol phthalein complexone method using BAPTA buffer. All the parameters are under Proficiency testing program with z-score below 2. All the parameters are under the scope of accreditation by the National Accreditation Body of India. Test methods adopted were IFCC certified.

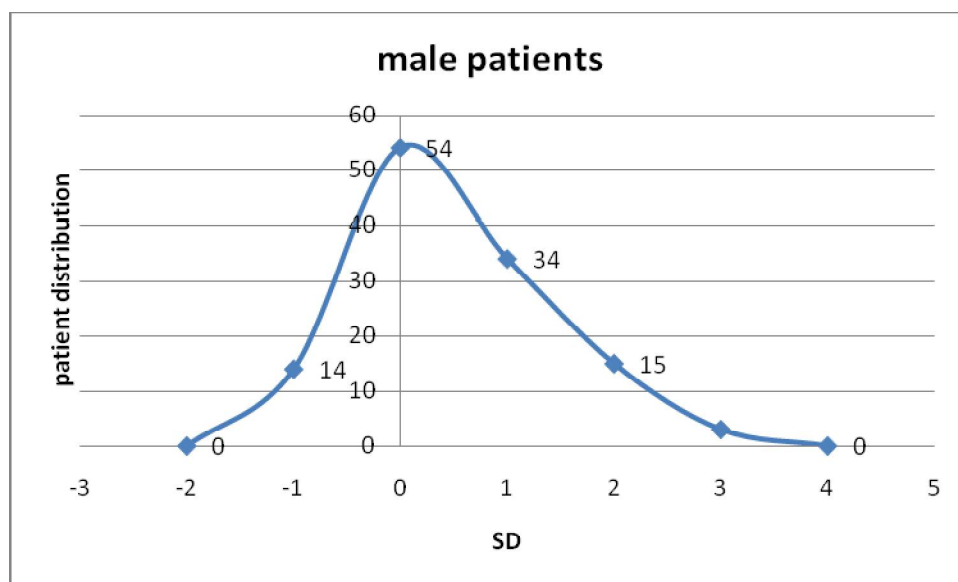
### Statistical Calculation

For BRI determination non parametric distribution analysis has been suggested by CLSI. But in the present study both parametric and non parametric distribution analysis were performed to evaluate the difference. In parametric statistical analysis only mean and SD for all the parameters tested were done. CV% determination is not applicable for population study due to wide variance in results. In non parametric statistical analysis 2.5percentile-97.5 percentile distribution was considered for reference range evaluation. For other parameters (UA, Ca, CRP, RF) mean and SD of the results were calculated. Textbook statistical guideline has been used for result analysis(11).

### Results and Discussion

The patient data would show why the determination of BRI was felt to be necessary. Almost 90% of the patient population were found out to be Vitamin D deficient as per manufacturer's range [ $\geq 30$  ng/ml]. The results & distribution of selected male patient population is given in Figure[1], Table [1]:

**Figure [1]: Parametric distribution of 25OHD of 120 male patients**



**Table [1]: Mean & SD of 25OHD,UA,Ca,CRP & RF120male patients**

Statistical	25OHD	UA(mg/dl)	Ca(mg/dl)	CRP(mg/L)	RF(IU/ml)
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Parameter	(ng/ml)				
Mean	17.57	5.31	9.24	3.86	10
SD	7.53	1.12	0.404	0.79	5

Y axis : number of patients in the range of -2SD to 4SD.

X axis: SD; 1SD is 7.53 ng/ml 25OHD .0:Mean value:17.57ng/ml[Table 1].

- On Y axis : exact number of patient within the SD range.

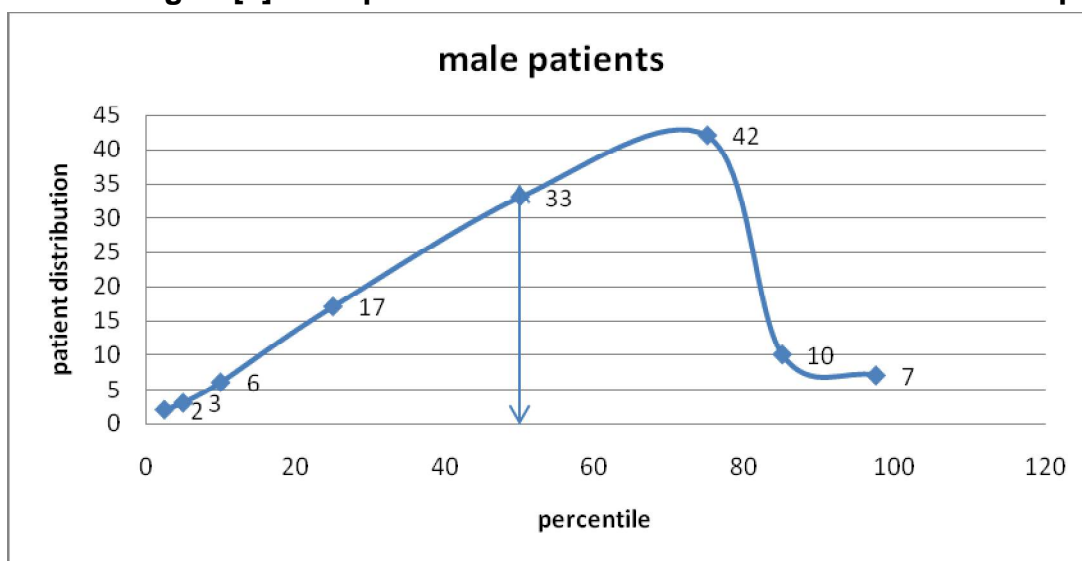
\*Same graphical pattern for Figures [1,3,5,7],Tables[1,3,5,7].

102 male patients were within  $\pm 1$ SD range(10.04-25.1ng/ml). Other parameters are within normal reference interval. Hence, non parametric distribution of 25OHD was done. For other parameters

BRI were already established. So, patient distribution analysis were not necessary.

The patient distribution in the parametric distribution curve suggests maximum population remains within -1SD to +2SD. The range is( 10.04 – 32.63 )ng/ml. The range covers 117 patients ie, 97.5% population.

**Figure[2]: Non parametric distribution of 25OHD of 120 male patients**



Median(similar pattern, Figure 2,4,6,8)

**Table [2]: 25OHD result distribution of 120 male patients**

Value(ng/ml)	Percentile	Number of patients
5.5	2.5	2
6.5	5	3
8.3	10	6
12.6	25	17
16.5	50	33
22.8	75	42

25.5	85	10
39.7	97.5	7

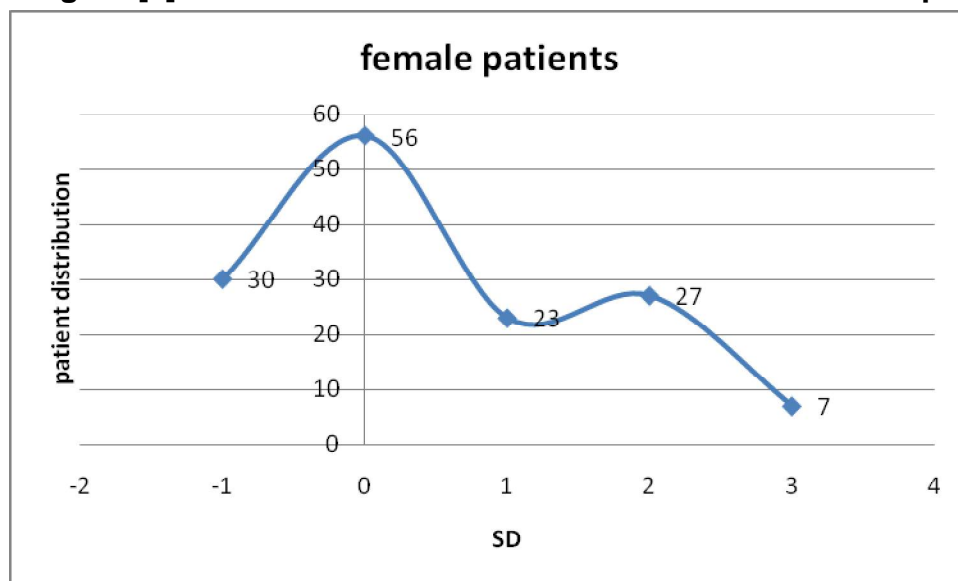
**Y axis : number of patients in the range of 0 to 100 percentile.**

**X axis: percentile range. Distribution as per [Table 2].**

- **On Y axis : exact number of patient within the percentile range.**  
**\*Same graphical pattern for Figures [2,4,6,8],Tables[2,4,6,8].**

10percentile to 97.5 percentile covers the total population. 95.8 percent of the male patient population are within the range of ( 8.3-39.7) ng/ml. The parametric and non parametric distribution data are very close. Non parametric distribution ranges are generally wider. The decision range for the male patient population is ( 8.3-39.7)ng/ml. Number of female patient data collected were 143. Number of collected data were more than 800 but the author eliminated other patients as per patient elimination criteria ie the patients priority supplemented with Vitamin D and age group not at par with healthy volunteers were eliminated.

**Figure [3]: Parametric distribution of 25OHD of 143 female patients**



**Table [3]: Mean & SD of 25OHD,UA,Ca,CRP,RF female patient population (143 patients)**

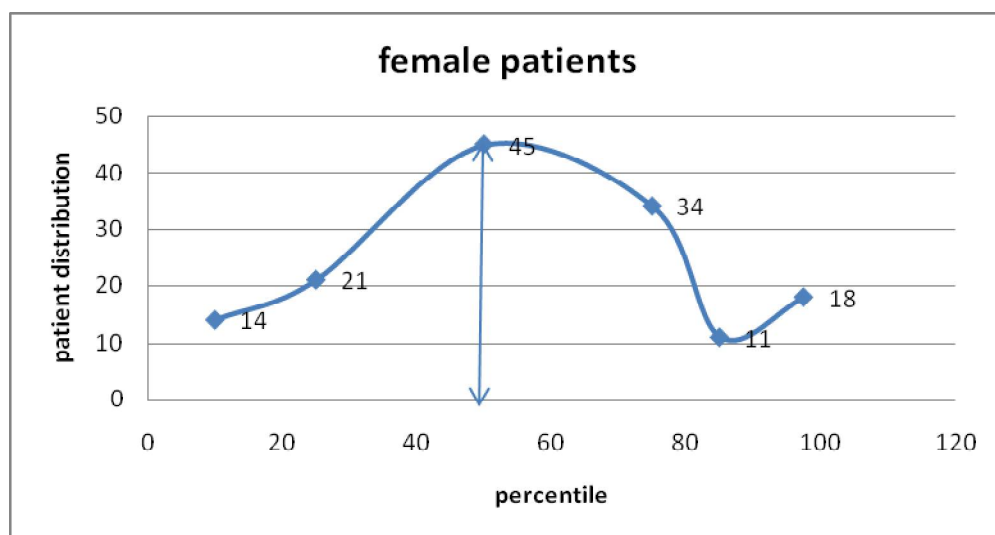
Statistical Parameter	25OHD (ng/ml)	UA(mg/dl)	Ca(mg/dl)	CRP(mg/L)	RF(IU/ml)
Mean	14.09	4.44	9.51	4.37	16
SD	11.53	1.4	0.66	0.49	5



The parametric distribution is uneven. Lower limit is -1SD but upper limit may be extended up to 3SD. Moreover, -1SD lower limit cannot be acceptable, as lowest limit becomes 3ng/ml which shows severe Vitamin D deficiency.

So, for female patient population only non parametric distribution study is preferred. However, the range as per graphical distribution is (3.65-48.68)ng/ml and optimal distribution range is 10.2- 39.7ng/ml, 75% of female patient population. The distribution is in accordance with Bischoff et al[7].

**Figure [4]: Non parametric distribution of 25OHD of 143 female patients**



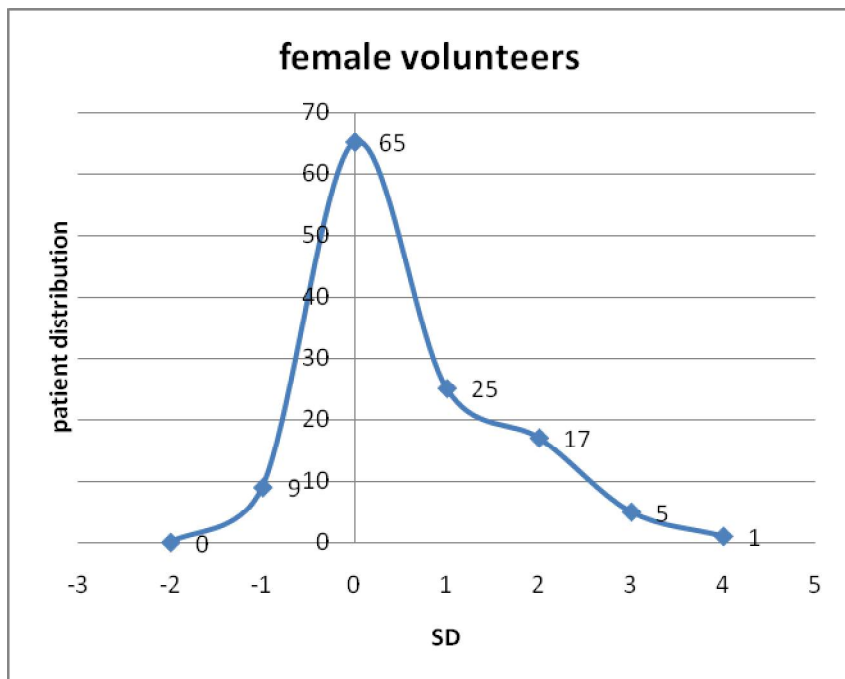
**Table[4]: 25OHD result distribution of 143 female patients**

Value(ng/ml)	Percentile	Number of patients
3	10	14
4.5	25	21
10.2	50	45
22.1	75	34
27.6	85	11
39.7	97.5	18

The pain profile data other than Vitamin D are well within normal range for both male and female patients & SD's are also having narrow range. The 25OHD of female patients are ranging from 3ng/ml to 39.7ng/ml and all the patients came with similar nature of complaint. The accumulated results raised the question about the extent of the contribution of 25OHD deficiency to such complaints and from which concentration of

25OHD the patients are to be considered as Vitamin D deficient. The joint pain, back ache and general weakness may be precipitation of so many factors but empirical correlation of such complaint with Vitamin D deficiency is likely to be a simplification process specifically when none of the patients were suggested to check the bone mineral density.

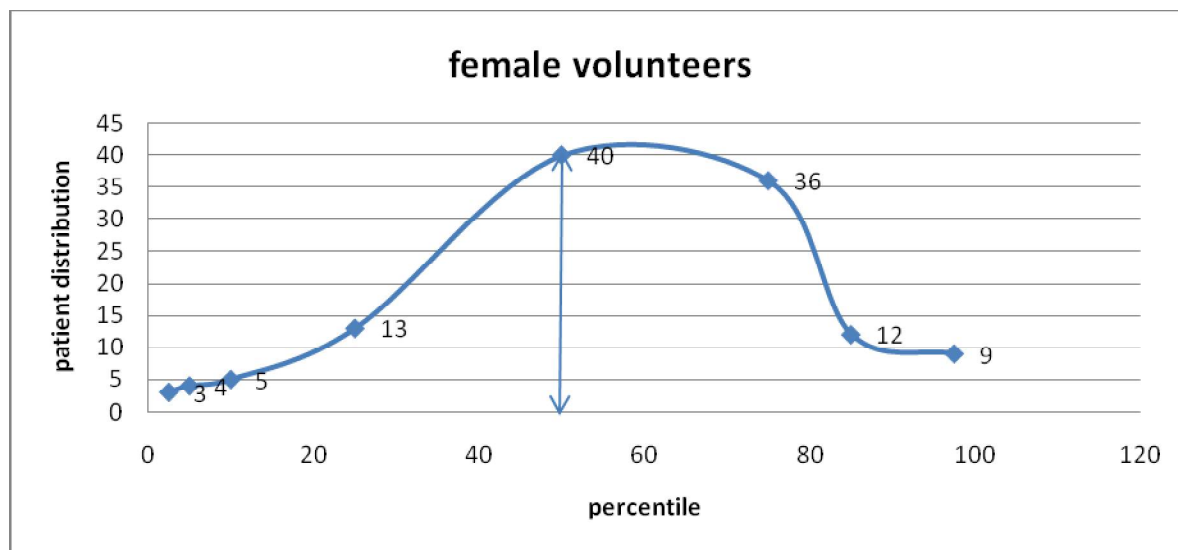
**Figure [5]: Parametric distribution of 25OHD of 122 female healthy volunteers**



**Table [5] : Mean & SD of 25OHD,UA,Ca,CRP,RF of 122 female volunteers**

Statistical Parameter	25OHD (ng/ml)	UA(mg/dl)	Ca(mg/dl)	CRP(mg/L)	RF(IU/ml)
Mean	15.52	5.03	8.9	3.55	15
SD	5.78	0.98	0.204	0.35	4.65

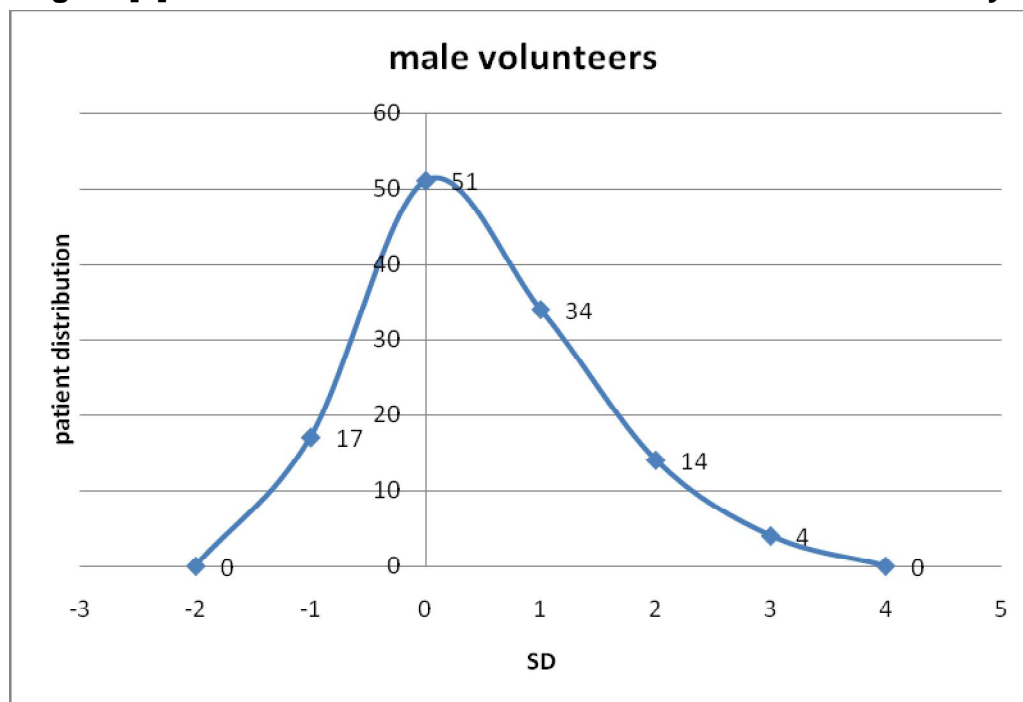
The results of healthy volunteers are comparable to patients. The distribution pattern suggests to consider the range from -1SD to +2SD. The range is (9.74- 27.08)ng/ml. The range covers 116 healthy volunteers ie, 95% of healthy female population. So, the history of pain and fatigue may not solely be attributed to Vitamin D deficiency(Figure6,table 6).

**Figure [6]: Non parametric distribution of 25OHD of 122 female volunteers****Table [6]: 25OHD result distribution of 122 female volunteers**

Value(ng/ml)	Percentile	Number of patients
7.7	2.5	03
8.0	5	04
9.0	10	05
11.5	25	13
14.6	50	40
18.5	75	36
20.6	85	12
32.0	97.5	09

The distribution of 10 percentile to 97.5 percentile ranges from (9.0-32.0)ng/ml and covers 94% population. The 2.5-5 percentile value ie,(7.7-8.0)ng/ml was felt to be the controversial range. Whether this range would be incorporated within BRI or to be considered as deficiency range , multicentre study only can give satisfactory answer. The author also studied the 25OHD results of male volunteers. Male volunteers were chosen as per the protocol mentioned .

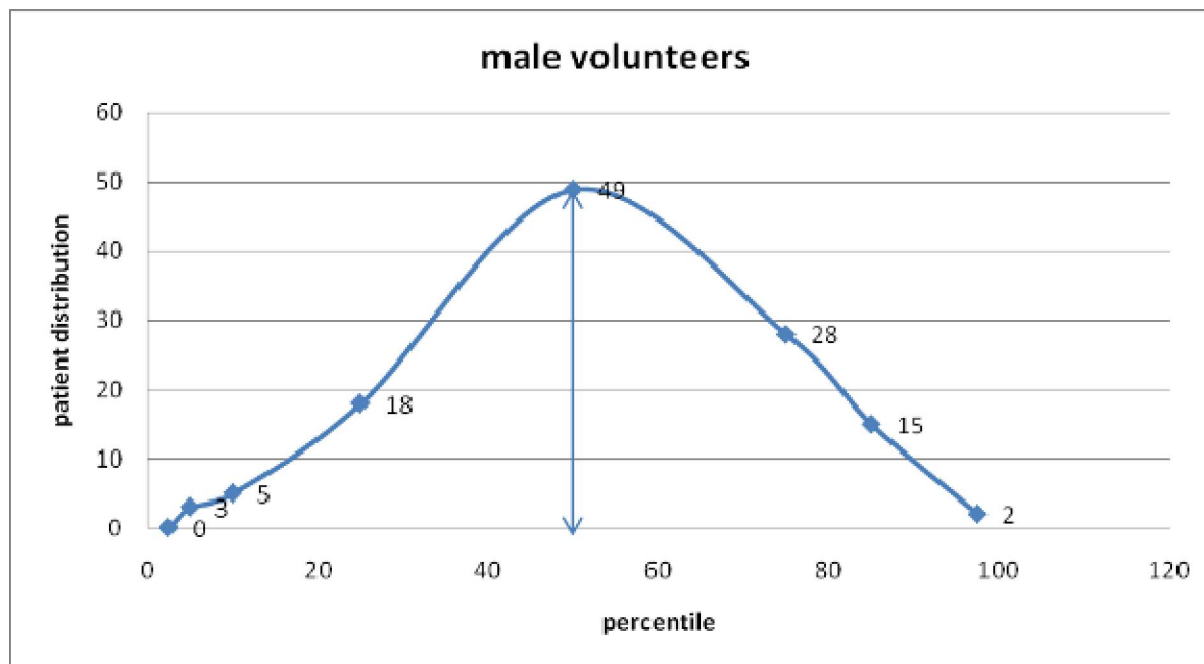
Total number of male volunteers were 120. The parametric distribution is being shown in figure[7] and table[7].

**Figure [7]: Parametric distribution of 25OHD of 120 male healthy volunteers****Table [7]: Mean & SD of 25OHD,UA,Ca,CRP,RF of 120 male healthy volunteers**

Statistical Parameter	25OHD (ng/ml)	UA(mg/dl)	Ca(mg/dl)	CRP(mg/L)	RF(IU/ml)
Mean	15.85	3.95	9.9	3.88	21
SD	9.6	0.75	0.22	0.45	5.35

The parametric distribution of male volunteers shows a range of (6.26 – 44.65)ng/ml. The whole population is coming under this range. The statistical correlation is uncommon as no statistical calculation ideally does cover 100% population range. The sunlight exposure history of 3SD range volunteers were taken. Some of them are found out to remain exposed to direct sunlight for 5- 6hrs per day. Another group gets direct exposure for 5-6 hrs and under indirect exposure for the rest of the day. The non parametric distribution has been shown in Figure[8] and table[8].

**Figure [8]: Non parametric distribution of 25OHD of 120 male healthy volunteers**



**Table [8]:25OHD result distribution of 120 male healthy volunteers**

Value(ng/ml)	Percentile	Number of patients
3.0	2.5	00
6.25	5	03
8.5	10	05
10.05	25	18
14.85	50	49
25.7	75	28
33.43	85	15
40.25	97.5	02

The expected normal range is (8.5-40.25)ng/ml, keeping the 2.5percentile value under consideration. The references ranges are compared with the consensus values of North Germany (1), recently revised reference range(12) published by Roche Diagnostics( Table 9) .

**Table [9]: Comparison of population survey results  
Parameter : 25OHD (ng/ml)**

Report obtained from	Age group	Number of Male	Reference Range	Number of Female	Reference Range
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	(years)	population	(ng/ml)	population	(ng/ml)
Consensus report, Roche, Northern Germany	20-77	201	6.23-49.9	252	4.92-42.7
Population study, Roche Diagnostics	Adults	Not available	11.1-42.9	Not available	11.1-42.9
Present study data (healthy volunteers)	25-60	120	8.5-40.25	122	9.0-32.0
Present study data (patient group)	25-60	120	5.5-39.7	143	3-39.7
Present study data (healthy volunteers) -Parametric distribution	25-60	120	6.26-44.65	122	9.74-27.08
Present study data (patient group) -Parametric distribution	25-60	120	10.04-32.63	143	3.65-48.68

The data obtained from the population study of West Bengal is correlating with the population study data of Roche Diagnostics. If health reference range is considered as optimal which is  $\geq 30$ ng/ml, 17% of male and 7% female volunteers satisfy the criteria. The lifestyle analysis of this specific volunteer group revealed that they are exposed to direct sunlight for more than 6 hrs (10am -4pm approximately) and indirectly exposed for the rest part of the day (8am-10am, 4pm-5-30pm approximately). It seems to obtain existing health reference range people need to get exposed for the whole day in a tropical country like India. Hence, it may be concluded that the whole patient group should not be considered as 25OHD deficiency group on the basis of the nature of complaints happened to be observed in 25OHD deficiency. Vitamin D is a fat soluble vitamin so use in excess is not advisable and the complaints of joint pain, body ache and general weakness may have several reasons other than Vitamin D deficiency. Current studies in India shown a table of UP (Uttar Pradesh, India) based data of 25OHD concentration in adults and children. The concentration range table [13] shown similarity in data presented by the author but the authors of the article concluded the situation as 25OHD hypovitaminosis and stated the situation as critical situation. Similar conclusion has been supported by Babu et al [14] and Gupta et al [15] suggesting Vitamin D fortification as remedial measure. But the conclusions were based on health reference range ie, considering the health reference range needs no re-evaluation. But sunlight exposure and dress code of West Bengal and UP are similar. To rule out deficiency /re-evaluation which one is the actual need of the situation the study to be taken up in Hilly & monsoon prone region where chance of exposure to sunlight is minimum.

The parametric distribution data analysis is generally not applicable for reference range determination. But in the present study the same has been done for all group and following observations were noted.

- *Two distribution analysis surprisingly resembles strengthening the conclusion.*
- *The empirical (Mean $\pm$ 2SD) calculation is not applicable for evaluation of BRI. The SD's are wide in population analysis. So, CV% calculation is not applicable. The graphical presentations show that mean and range to be determined as per patient distribution. Hence, reference range may be considered from -1SD to +3/4SD. In such situation mean to be calculated after taking decision about the range. As an example, the mean of male volunteers is 15.85ng/ml. But -1SD is the minimum range where as maximum value distributed upto 3SD. Evaluation as per the distribution analysis gives the range (6.26-44.65) ng/ml. Similar calculations has been applied for both patient and healthy population group. Close resemblance of reference range which strengthened the conclusion.*

### **Conclusion**

- The health reference range should be re evaluated for any parameter in situation/ situations of confusion.
- The reference range of the parameter felt to be re-evaluated as the result analysis of the patients shown negative bias. The reference range ideally should have no bias. The laboratory medicine practitioners are expected to observe such bias and take necessary action.
- It is being mentioned as mandatory note that the laboratories should evaluate the local reference range as and when necessary. So, such evaluation study helps cross verification of existing health reference range also.
- In the present situation the re-evaluation was need of the situation. The laboratory is presently mentioning the evaluated reference range as "Laboratory Defined Reference Range" in the test results.
- Whether India should start fortification/ evaluate reference range? Considering fortification is essential the hypovitaminosis could have been reported by this time. Till date, articles gave situations of 25OHD hypovitaminosis and requirement of fortification but no presentation of data on number of affected population due to such hypovitaminosis.

### **Limitations of the study**

- *The study should have been multicentric study. A study in Hilly and monsoon affected region is essential.*
- *Exposure of sunlight varies with season. Whether seasonal and difference in clothing affects the reference range yet to be studied.*
- *Bone Mineral Density study results of the patients and volunteers would have added to a concrete conclusion. But the test is very expensive , the project had no fund support and suggestion of bone mineral density test is Clinicians option.*

**Consent**

The author obtained consent from patients. Volunteers were informed about the study .

**Ethical issue:**

The results are test results. Patient identity has not been disclosed. The author obtained consent of the patients and volunteers also. So, no ethical issue would be raised or was raised during the study.

**Competing Interest:**

Not applicable.

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## 9

### STUDY OF PR INTERVAL IN FEMALES OF DIFFERENT AGE GROUPS

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#### ABSTRACT:

**INTRODUCTION:** PR interval is the interval between the onset of P wave and the onset of QRS complex. The normal PR interval is in the range of 0.12-0.28 sec Prolonged PR interval may be due to delayed conduction from atria to ventricles. Sometimes prolonged PR interval is seen in clinically healthy patients. In females till menopause the blood pressure is less than males of same age group due to protection by oestrogen. After menopause risk of hypertension and also heart diseases increases. Again increasing age itself is responsible for degenerative changes in body. So this study was done for variation in PR interval in females with increasing age.

**AIM & OBJECTIVE:** To study PR interval variations in females of different age groups.

**MATERIAL & METHOD:** Females of different age from 20 years to 80 years were studied. ECG in lead II was recorded using Power lab 8/30 series. Mean standard deviation & proportion was used to present the data. Student's 't' test was done. Pearson's correlation coefficient 'r' was used to examine relationship between ECG changes with difference age groups. A two tailed p-value less than 0.05 will be considered as significant.

**RESULTS:** Prolongation of PR interval with increasing age

**CONCLUSION:** Although clinically healthy, females with prolonged PR interval must be advised regular follow up to detect early cardiac insufficiency.

**KEY WORDS:** PR interval, ECG, Females, Age

**INTRODUCTION:** The time between the beginning of the P wave and the beginning of QRS complex is PR interval. It indicates the interval between the electrical excitation of the atria and the beginning of electrical excitation of the ventricles.<sup>1</sup> When there is tachycardia PR interval usually decreases in length and with bradycardia PR interval increases. PR interval more than 0.20 sec is said to be prolonged PR interval. Patients with PR interval more than 0.20 sec are considered to have first degree heart block. In first degree heart block PR interval is prolonged up to 0.30 sec. The first degree heart block is due to delay of conduction from atria to ventricles but blockage of conduction is not seen. When PR interval increases above 0.35 sec to 0.45 seconds, conduction through the AV bundles is severely depressed and conduction stops entirely. Thus PR interval is very useful parameter to determine severity of heart disease.<sup>2</sup> Changes in conduction, voltage, and electrical axis may be seen in the aged person due to aging process. The age related electrocardiographic changes may also be due to coronary artery diseases. Also incidence of heart disease increases with age. In females after menopause risk of hypertension and therefore risk of cardiovascular diseases increases due to loss of protection by oestrogen hormone. Therefore we studied PR interval in females of different age groups to find out variations in PR interval with increasing age of females.

**MATERIAL & METHOD:** The study was done in Jan 2012 to Dec 2012, at department of Physiology Navodaya Medical College Raichur, Karnataka, India. The healthy females of different age groups were included in the study. The subjects were recruited from general population in and around Raichur. Ethical clearance was obtained from the Navodaya Medical College Ethical Committee for Human Research to conduct the study. Written consent was obtained from the participants after explaining them the purpose of the study and details of the procedure. Healthy females in the age group 21 to 80 years were included in the study. H/O any systemic diseases like Hypertension, Heart diseases, Diabetes mellitus and H/O Smoking, alcohol consumption and medication. 75 female subjects who satisfied the inclusion and exclusion criteria were recruited. All the subjects were divided into different subgroups according to their age, Group I: 21 – 40 years (25), Group II: 41 – 60 years (25), Group III: 61 – 80 years (25). For all the subjects a detailed history followed by clinical examination was carried. Blood pressure was recorded in supine position after relaxing for 5 minutes. The subjects were asked to take rest for 10 minutes. Then Lead II ECG was recorded on all subjects in supine position in an ambient temperature for 3 minutes by using Power lab 8/30 series with dual bio amplifier (Manufactured by AD instruments, Australia with model no ML870). And the analysis of the ECG was done by the software in the same instrument.

Descriptive statistics such as mean standard deviation and proportion was used to present the data. Students't test for parametric data was used for comparison between groups. Pearson's correlation coefficient 'r' was used to examine relationship between ECG changes with difference age groups. A two tailed p-value less than 0.05 will be considered as significant<sup>3,4,5</sup>

### RESULTS:

**Table 1: Comparison of blood pressure between females of different age group**

Parameters	Group I	Group II	Group III	Post hoc multiple Comparison
Mean SBP (mm of Hg)	115.8 ± 6.2	120.8 ± 9.6	129.7 ± 13.4	Gr I vs II, p>0.05 Gr I vs III, p<0.001* Gr II vs III, p<0.001*
Mean DBP (mm of Hg)	74.6 ± 6.3	79.04 ± 5.7	81.04 ± 5.75	Gr I vs II, p<0.05 Gr I vs III, p<0.001 Gr II vs III, p>0.05

\* Statistically significant

There was statistically significant difference in SBP when compared between group I and III and between group II and III. There was statistically significant difference in DBP when compared between group I and II and between group I and III.

**Table 2: Comparison of PR interval between females of different age groups**

Parameters	Group I	Group II	Group III	Post hoc multiple Comparison
Mean PR Interval (s)	0.13 ± 0.06	0.14 ± 0.04	0.15 ± 0.03	Gr I vs II, p>0.05 Gr I vs III, p>0.05 Gr II vs III, p>0.05

\* Statistically significant

PR interval was within normal range in all the age groups. There was prolongation of PR interval with increase in age. But this prolongation was statistically insignificant.

**DISCUSSION:** Aging is natural Physiological process. As age advances degenerative changes start in body affecting all systems. Blood pressure increases progressively as age increases. Systolic blood pressure increases more than diastolic blood pressure during middle adult years. Systolic blood pressure continues to increase till age of 80 years to 90 years. Diastolic blood pressure may remain constant or it may decrease after age of 50 years to sixty years. This leads to rise in pulse pressure progressively with age and the rate of rise is more after age 50 years<sup>6,7,8</sup>The fall in DBP seen after

age 60 years is due to increased large artery stiffness<sup>9-14</sup>. Age-related stiffening of the aorta leads to decreased capacity of the elastic reservoir and also leads to greater peripheral runoff of stroke volume during systole. Therefore less blood is remaining in the aorta at the beginning of diastole, and with diminished elastic recoil, diastolic pressure decreases with increased steepness of diastolic decay<sup>15</sup>. Gender related difference is seen in blood pressure trends. In females rise in blood pressure starts lower than in males and after 60 years age blood pressure becomes slightly higher in females than males. The increase in blood pressure with age is mostly associated with structural changes in the arteries and especially with large artery stiffness<sup>6,7,8</sup>. In our study there was increase in both SBP and DBP with increasing age of females and the increase was less in older age group compared to younger ones. The diagnostic accuracy of ECG to differentiate between 'Normal' and 'Abnormal' depends on analysis of distribution in 'Normal', i.e. clinically healthy, population<sup>16</sup>. Age is biologically most important variable. ECG parameters may show variations according to changes in age. In some of the studies a small but significant increase in PR interval with age is seen<sup>17</sup>, but in some studies it is not seen<sup>18</sup>. In the study done by Datey and Bharucha, there was no change in PR Interval in any of the electrocardiographic leads<sup>19</sup>. But many studies have shown a small increase in PR interval in aged person in different leads without any obvious clinical significance. Prolongation of PR interval indicates prolonged A-V conduction with A-V nodal block<sup>20</sup>. Recent studies showed that conduction of A-V node is accelerated resulting in decreased PR interval in ischemia<sup>NR21</sup>. Prolongation of PR interval is also now found to be associated with thyrotoxic periodic paralysis<sup>22</sup>. In our study we have noted a small increase in PR interval (within normal range) with increasing age of females. But this prolongation was statistically insignificant.

**CONCLUSION:** Due to degenerative changes with increasing age, arteries become stiff leading to myocardial insufficiency. Also after menopause females are more prone for hypertension and cardiovascular diseases. Therefore although clinically normal, the females with prolonged PR interval should be advised regular follow up to detect early cardiovascular insufficiency or any other cause.

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Schouten E G, Dekker J

## **10 STUDY OF EPIDEMIOLOGICAL PROFILE OF PRETERM DELIVERIES**

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### **ABSTRACT**

**Objective:** To study the epidemiological profile of preterm deliveries

**Study Design :**Retrospective Observational Study

**Duration of Study :**1 year : June 2014 to May 2015

**Patient and Methods :**Data was collected from the case papers of pregnant women and their outcome was studied .

**Results :**As many as **10%** of products of conception end up being delivered prematurely<sup>2</sup>

**Conclusion :** Most common causes of neonatal mortality can be attributed to prematurity or related complications. By studying the epidemiological profile of premature deliveries, causes can be classified as **preventable, partially preventable and non-preventable**.<sup>3</sup>By identifying preventable causes of preterm deliveries and providing necessary timely interventions, many-a- lives can be saved. Our study was a small step in realizing this dream.

**Key words:** Pre-term, Sepsis, Outcome, Maternal age, incidence, sex predisposition, Causes, Mortality outcome.

## INTRODUCTION

*Preterm is defined as babies born alive before 37 weeks of pregnancy are completed.*

*There are sub-categories of preterm birth, based on gestational age:*

*extremely preterm (<28 weeks)*

*very preterm (28 to <32 weeks)*

*moderate to late preterm (32 to <37 weeks).*

*In 2012, WHO and partners published a report "Born too soon: the global action report on preterm birth" that included the first-ever estimates of preterm birth by country<sup>4</sup>. More than three-quarters of premature babies can be saved with feasible, cost-effective care, e.g. essential care during child birth and in the postnatal period for every mother and baby, antenatal steroid injections (given to pregnant women at risk of preterm labour and meeting set criteria to strengthen the babies' lungs), kangaroo mother care (the baby is carried by the mother with skin-to-skin contact and frequent breastfeeding) and antibiotics to treat newborn infections.*

## OBJECTIVES

1. To find **prevalance rates and causes** of preterm deliveries in a tertiary care hospital in a period of 1 year amongst randomly chosen 1000 deliveries and make necessary interventions to prevent morbidity and mortality
2. To identify the outcome of prematurely delivered babies and look for intra-partum or peri-partum ways to modify them.

## METHODOLOGY

**Study Model:** Retrospective Observational Non-interventional Study of 100 cases year amongst randomly chosen 1000 deliveries.

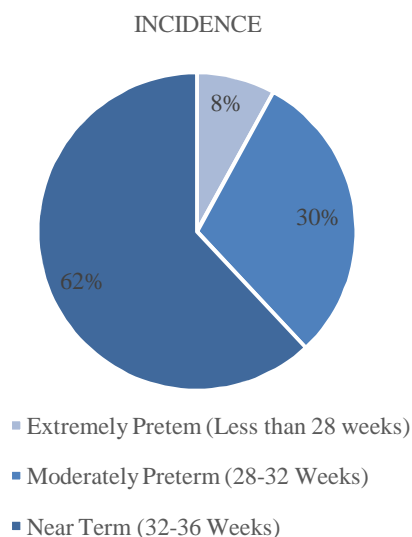
**Study Period:** 1<sup>st</sup> June 2014 to 31st May 2015

**Study Site:** NHL MMC, Smt. S.C.L. General Hospital

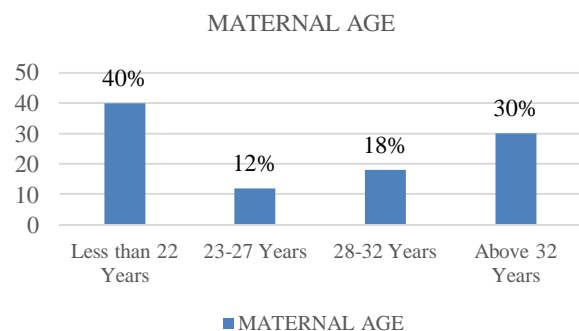
**Method:** Data was collected from the case papers of pregnant women and their outcome was studied.

### **OBSERVATION & DISCUSSION**

**Table 1 : INCIDENCE OF PRETERM BIRTHS**



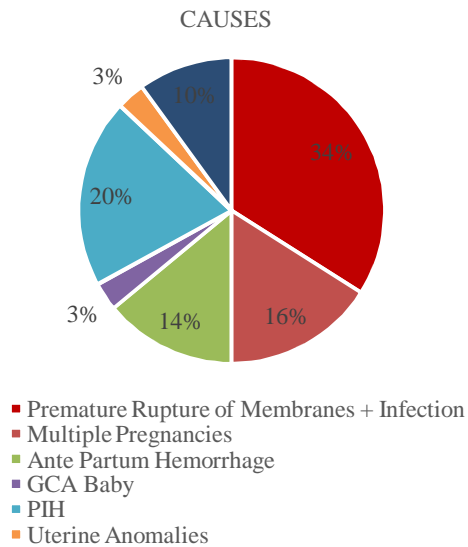
**Table 2 : Maternal Age related Distribution of Preterm Births**



On graphical representation this shows a **biphasic curve**. A teenage mother as well as an elderly mother are more likely to deliver preterm babies.

Most of the multipara in this study belonged to **low socio economic societies** who are more prone to nutritional deprivation, unhygienic conditions and lack antenatal care which ultimately results in preterm birth. Teenage mother results due to early marriage and lack of contraception knowledge. **Advanced maternal age** is mostly associated with genetic abnormalities, maternal malnutrition, prior preterm births and fetal loss.

**Table 3 : Causes of Preterm Labor**



Causes can be **medical or obstetrical**, however most often the cause of prematurity remains unknown.

**Premature rupture of membranes** occurs before 37 weeks and is the highest, PROM mostly results in oligohydramnios and chorioamnionitis both of which result in preterm deliveries.

2<sup>nd</sup> highest cause of preterm birth is PIH, **pregnancy induced hypertension results in placental changes.**

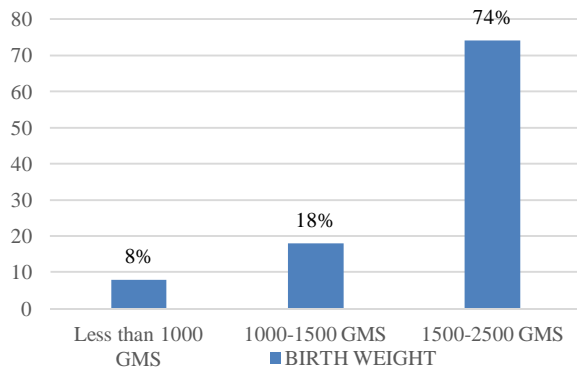
Increase in IVF programs has resulted in increase in **multiple gestation**. Multiple gestations are associated with overdistention of the uterus which results in preterm rupture of membranes and preterm delivery. Preterm births result more in abruption due to uterine contractions.

**Miscellaneous reasons** which includes stress, tobacco chewing, nutritional challenge, cervical incompetence, alcohol abuse.

**Table 4 :Distribution according to Birth weight in preterm babies**

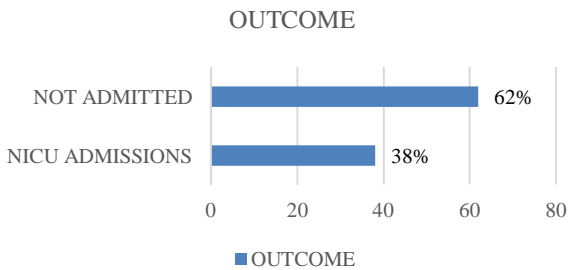


## BIRTH WEIGHT



Most of the babies are Between 1.5 and 2.5 g. Those below 1.5 Gms who require respiratory support, they may need ventilation or CPAP where the baby does the work of breathing with some extra air pressure to keep the lungs open

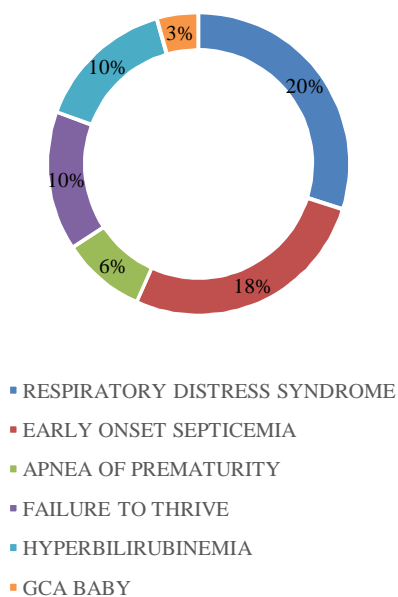
**Table 5 :NICU Admission**



Out of the 100 preterm delivered babies **38 were found to have been admitted in NICU due to respiratory, hemodynamic and metabolic instability** which makes it difficult for the baby to survive in extra uterine life. **Respiratory illnesses** including the lower respiratory tract infection are the dominant cause for hospital admission. More babies survive premature birth, but serious health problems remains unchanged.

**Table 6 : Complications in NICU Admissions**

COMPLICATIONS IN NICU ADMISSIONS



The most common cause for which the babies are admitted is **respiratory distress syndrome**, here the babies have breathing difficulties due to lack of agent surfactant in the lungs, treatment includes ventilator or CPAP, steroids before delivery reduces the risk.

2<sup>nd</sup> most common cause is **early onset septicemia**, infections are common because of a much compromised immune system, and serious infections commonly seen are pneumonia, sepsis and meningitis.

#### CONCLUSION:

1. As many as **10%** of products of conception end up being delivered prematurely<sup>2</sup>N
2. A number of factors in **the mother, the placenta and in the baby** can result in preterm birth.
3. Preterm births are on the rise due to **increased frequency of multiple births, young or advanced maternal age, low BMI, short inter pregnancy intervals, pre existing , non-communicable diseases, hypertensive disorders of pregnancy, infections and increasing psychological stress.**
4. Interventions to reduce the morbidity and mortality of preterm birth can be:
  - **PRIMARY** - which is directed to all the pregnant women, which includes Routine antenatal carebehavioural, social and financial support to women, health education for all women

- **SECONDARY-** *which is aimed at eliminating or reducing existing risk on the basis of obstetric history eg, a previous preterm birth or unknown uterine anomaly or present pregnancy risk factors eg, multiple gestation, bleeding, pre-eclampsia, IUGR, diabetes, thyroid disease, heart disease, asymptomatic bacteriuria*
- **TERTIARY-** *interventions that can prolong pregnancy and improve health outcomes and survival for the premature baby, antenatal transfer of the mother and the fetus to a hospital equipped to care for preterm infants, antibiotic treatment of PROM delays labour, prevents neonatal infection and cerebral damage, antenatal administration of corticosteroids to the mother reduces the neonatal morbidity and mortality, administration of magnesium sulphate to women at risk reduces the rate of cerebral palsy and improves long term neonatal health outcomes.*

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## 11 A STUDY OF BRANCHING PATTERN OF SECONDARY BRONCHI.

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### ABSTRACT:

**BACKGROUND:** Lungs, the pair of respiratory organs are made up of independent functional units called bronchopulmonary segments, each having its own segmental/ tertiary bronchus. Not much significant evidence is available for the variations in branching of secondary bronchi.

**AIM:** The present study was undertaken with an aim to discover the variations in the branching pattern of secondary bronchi of both the lungs.

**METHOD:** Ten casts – 6 male specimens and 4 female specimens, of tracheobronchial tree prepared from silicone gel using luminal cast plastination method were used for this study. The pattern of division given in Gray's textbook of Anatomy (35<sup>th</sup> edition) was used as a reference.

**RESULTS:** The variations were found in 4 out of 10 (40%) specimens on right side and 3 out of 10(30%) specimens on left side. Moreover, in males, 3 out of 6 (50%) on right side and 1 out of 6 on left side (16.67%). In females 25% on right side and 50% on left side varied.

**CONCLUSION:** Thus the study indicated that the variations in the branching pattern of secondary bronchi occurs on both the sides in both sexes in significant percentages.

**LIMITATION of the study:** The sample size of this study was too small.

**SUGGESTION for further research:** It is suggested that the present study should be extrapolated with large sample size.

**KEYWORDS:** secondary bronchi, tertiary bronchi.

### INTRODUCTION :

Human Anatomy is a science of facts about structures and their variations. Dissection is a routine and irreplaceable means to explore this existence. Due to the advancement of technology, newer techniques to unravel the facts are being adopted. The preservative formalin has its own hazards like carcinogenesis, allergic contact dermatitis, rhinitis, conjunctivitis. These side-effects can be reduced by adjuncting the teaching with the specimens produced by other methods which do not have such toxic hazards.

One such method of preparation of the dry, colored, non-toxic, durable, odorless, natural-looking specimens is plastination. Plastination is a new art in science. Luminal cast plastination using silicone gel is one of the methods of plastination to obtain the negative replica or mould of a tubular structure e.g. tracheobronchial tree, arterial - venous - ductal branches and their variations. The principle involves the filling up of the lumen with the material and dissolving the surrounding tissue.

Lungs, the pair of respiratory organs are made up of independent functional units known as bronchopulmonary segments, each having its own tertiary or segmental bronchus. There are ten segmental bronchi on each side. The spread of infection or carcinoma may be limited to one segment only. An accurate anatomical knowledge of the various parameters – length, transverse and anteroposterior diameters of the various bronchi and sub-carinal is of immense importance in the surgical resection and reconstruction of any part of the lung. These informations have potential applications for studies in pulmonary physiology and anaesthesiology as well as for the conduction of some maneuvers like endotracheal intubations and bronchoscopic procedures (diagnostic, therapeutic and combined) with skill and perfection.

This is used to prepare the tracheobronchial tree casts from lungs along with trachea specimens which were used to study the variations of secondary bronchi.

**AIMS and OBJECTIVES:**

The aim of the present study was to study the variation in the branching pattern of the secondary bronchi.

**Material and Methods:**

The present study was carried out after seeking the permission from the Institutional Ethical Committee for Human Research (IECHR), Medical College, Baroda, Gujarat, India.

**1. Study design :** *Retrospective observational study*

- 2. Sample size:** *It is a feasibility sample and time bound sample. Ten fresh specimens of trachea with intact lungs obtained from the forensic medicine department from the unclaimed bodies. The cold room record shows that on an average there are four unclaimed bodies a month out of which excluding the damaged bodies and other exclusion criteria two specimens can be obtained per month. The procedure for making one cast requires on an average 5 days. Thus considering the period of data collection from April 2013 to November 2013, the sample size is kept to be 10.*

**3. Inclusion criteria:**

- *Undamaged specimens of trachea with lungs of any age and sex.*

- *Normal spongy texture of lung parenchyma on grossing of specimens.*

#### **4. Exclusion criteria :**

- *Tracheostomised patients.*
- *History of respiratory infections before death or lung cancer if available.*
- *Nodules or abnormal consistency of lung parenchyma on grossing.*

#### **MATERIALS USED:**

- *Jars for storage and processing,*
- *Fresh human lungs with trachea*
- *Detergent*
- *Hydrogen peroxide*
- *Injecting gun and silicone gel tubes*
- *Dissection instruments, gloves and mask.*
- *Concentrated acid for maceration*

#### **METHOD:**

- *A. The method of preparation of luminal cast:*
- *The fresh specimen collected is washed with detergent and hydrogen peroxide till the clean water comes out of the lumen of the trachea. It take over 3-4 hrs of continuous cleaning. The air is passed in the trachea using an air compressor for an hour to remove the water from the lungs which comes out from the pulmonary vessels and lung parenchyma.*
- *The silicone gel is injected into the lumen with the injecting gun till a firm pressure is felt and the resistance to the flow of the silicone into the tracheal lumen.*
- *The filling end is tied with a thread and the specimen is kept in a bucket of water overnight so that equal pressure is distributed over it from all the sides.*
- *The specimen is put in the concentrated acid for maceration for 2-3 days.*
- *Wash the specimen under running water to slough off the remaining tissue. The cast is ready for inspection.*
- *Ten fresh specimens of trachea with lungs were collected, 6 were males and 4 were females, the mean age was 49.6yr for males (41-60 yr) and for females it was 54 yr (41-60 yr).*

#### **OBSERVATION and RESULTS:**

- a. A subapical bronchus is found arising just 2mm below the apical bronchus in right inferior lobe bronchus of one specimen out of six male specimens studied.
- b. Medial segmental bronchus arises as an independent stem rather than the common anteromedial stem in right inferior lobe bronchus in three specimens out of total 10 studied. Two out of six male specimens and one out of four female specimens.
- c. The posterior and lateral segmental bronchi in lower lobe arise independently from the parent stem rather than the common stem in left lower lobe in two specimens one out of six male specimens and one out of four female specimens.
- d. In one specimen out of four female specimens the three segmental bronchi- anterior, apico-posterior and the stem for lingular bronchii arise directly from the upper lobe bronchus at the same level.

The variations were found in 4 out of 10 (40%) specimens on right side and 3 out of 10(30%) specimens on left side. Moreover, in males, 3 out of 6 (50%) on right side and 1 out of 6 on left side (16.67%). In females 25% on right side and 50% on left side varied.

## **DISCUSSION:**

As described by John W. et al in their study on Variant bronchial anatomy- CT appearance and classification, an accessory superior segmental bronchus <sup>(12)</sup> is found in the present study whose photograph is shown with observations. This variation is found on the right side which consists of two closely spaced bronchi that bridge the site of origin of the apical segmental bronchus.<sup>(12)</sup> Moreover, Atwell.S.W et al, in their article suggest that most bronchial anomalies are on the right and supernumerary superior segmental bronchus and tracheal bronchus are most common findings.<sup>(18)</sup>

The present study was undertaken as a preliminary project to have a 'hands-on' luminal cast plastination technique. The method was devised for our laboratory setting and a small study conducted on 10 samples which was purely dependant on the availability of the unclaimed specimens at the Forensic Medicine Department.

Hence, a further extensive study with more number of specimens and all age-groups is recommended.

## **CONCLUSION:**

*The present study gave a hands-on for luminal casting plastination technique, which is an emerging and evolving art in science.*

*The casts produced were beautiful, anatomically precise, giving a three-dimensional insight of the branching pattern of the tracheo-bronchial tree.*

Moreover, the sexual difference between various parameters is clearly evident and can be demonstrated.

The variation was found in the branching pattern of the secondary bronchus of the lower lobe.

These casts may be used for undergraduate teaching in colleges or for patient-education during pre-surgical counseling.

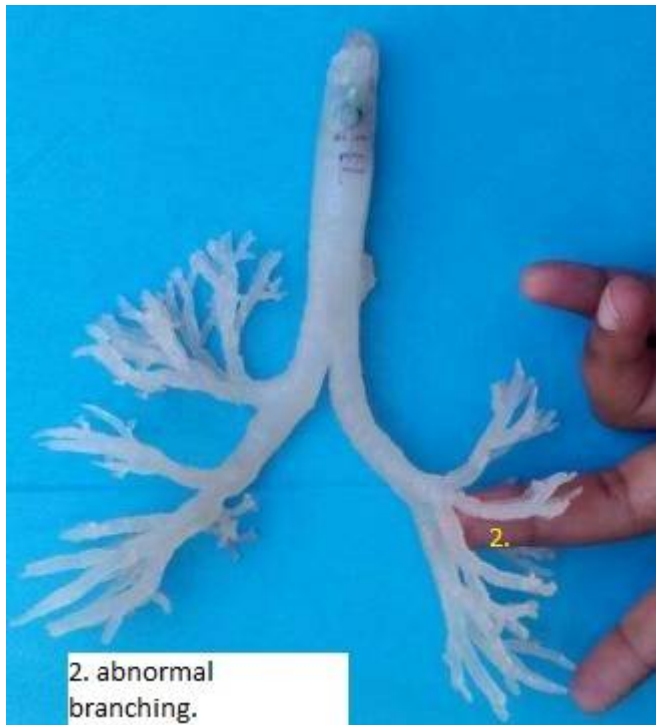
To conclude, the luminal cast plastination proved a good technique to produce the anatomically precise casts which were used for the study of variations.

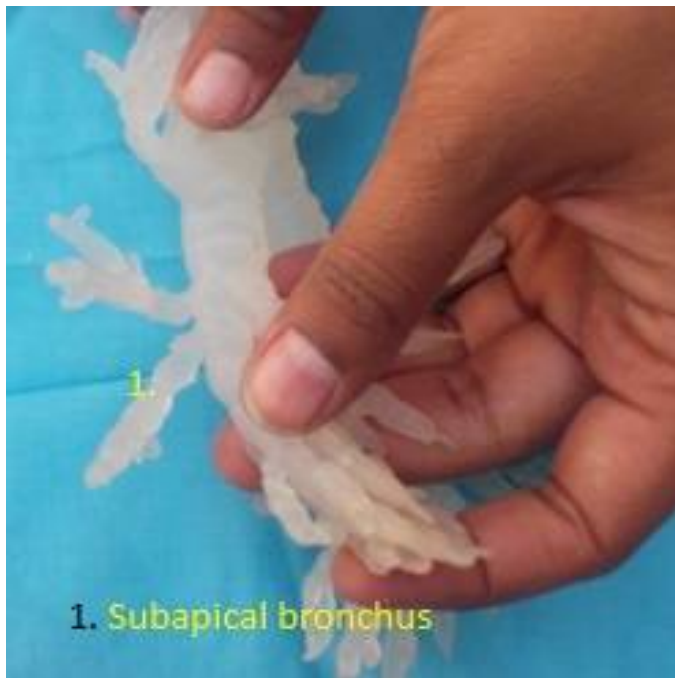
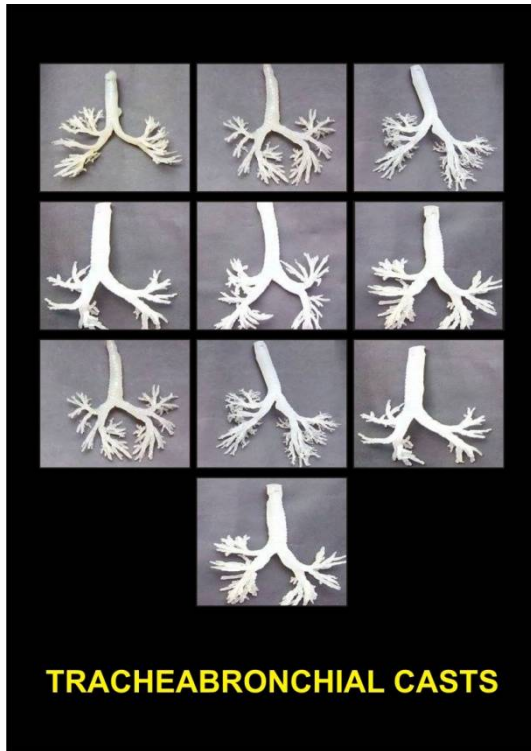
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## **12 IMPACT OF ACUTE PARTIAL SLEEP DEPRIVATION ON S.L.C.T. AS A TEST FOR ATTENTION SCORE ON MEDICAL STUDENTS: a comparative study**

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**Abbreviation: SLCT =single letter cancellation test**

### **ABSTRACT**

**INTRODUCTION:** sleep is an essential function of brain and help to maintain of attention and concentration. Sleep deprivation lead to difficulty in maintaining attention and concentration. Some medical students study hard at cost of sleep to the extent that is from few hours to total loss of sleep and may lead to many consequences and problems .The medical examination is a complex task and require due attention , concentration complex sensory motor and cognitive coordination, and sleep deprivation is hazardous.

**OBJECTIVE:** The goal of our study was to evaluate the impact of sleep deprivation on attention task studied by **single letter cancellation test (SLCT)** amongst the sleep deprived first MBBS students compared to students who had taken adequate sleep.

**METHOD:** In laboratory set up, two groups of students Group n1=25 students of Normal sleep group (19 males, 6 females;) of mean age  $18 \pm 1.43$  ,and group n2=23, sleep deprived group (19 males, 4 females;) of mean age  $18 \pm 1.53$  years were chosen randomly. On the day one preliminary examination after taking history of sleep deprivation and drug history ,caffeine consumption and consent, subjects were instructed to conduction **single letter cancellation test (SLCT)**..The score of the test were compared among both the group and statistical t-test was carried to know the significant of difference in test score .

**RESULTS:** The results indicated that Group n2 23 subjects [sleep deprived group], performed inferior to group n1 25 Normal sleep group. This suggest that attention, concentration and visual signal interpretation, speed, spatial orientation was significantly affected by sleep deprivation studied by SLCT.

**CONCLUSIONS:** Sleep deprivation leads to poor outcome of test of ability to focus selectively by SLCT. Sleep deprivation significantly influence attention parameter i.e. studied by **single letter cancellation test (SLCT)** and reduce the attention modality. The attention and concentration are essential parameter for good outcome of medical examination especially practical examination performance. Thus, it is recommended that in workplace/college i.e. medical students should be strongly recommended to avoid sleep deprivation and take adequate sleep for healthy performance in practical examination. Sleep hygiene can taught to avoid sleep deprivation. Yoga, relaxation and breathing techniques good alternative for stress management in such set up.

**KEY WORDS:** *sleep, deprivation attention and concentration,, SLCT, medical students*

### **Introduction:**

Irregular sleep schedules are highly prevalent among medical college students, As per one report as up to 70% of the students attain insufficient sleep. The consequences of sleep deprivation can result in increased risk of academic failure, compromised learning, impaired mood, and increased risk of motor vehicle accidents including depression,. This article reviews the current prevalence of sleep deprivation among first MBBS students and compare the impact of sleep deprivation on single letter cancellation test.

Because of complexity of sleep, reducing sleep hour due to internet, TV, Media sleep research demand due attention to physiology laboratory. Objective assessment of impact of sleep on attention parameter is a also a complex. Large number of tests are available neuropsychology and neurology to assess attention. Tests of attention usually depends on three sources of information: 1) psychometric tests designed to measure other cognitive functions, which provide indirect information about attention; (2) specific neuropsychological tests of attention; and (3) direct behavioral observation and measurement to assess attention. The measure of concentration is the span of time in which focus on a single task can be maintained. In this study, attention was assessed by single letter cancellation test and compared amongst group of student have normal sleep of 6-8 hour and Sleep deprived group of students. "Everyone knows what attention is," wrote William James in his Principles of Psychology (1890). "It is the taking possession by the mind in clear and vivid form, of one out of what seem several simultaneously possible objects or trains of thought...It implies withdrawal from some things in order to deal effectively with others, and is a condition which has a real opposite in the confused, dazed, scatterbrained state." Attention is important to learning. Learning is most efficient when a person is paying attention.

### **MATERIALS AND METHODS:**

The present study comprises of 25 subjects of normal sleep group n1 and 23 subjects of sleep deprived group n2 First MBBS students .N1 group of student who slept normal sleep  $\geq 6$  hours and second group sleep deprived who slept (0 to  $\leq 3$  hours) in night.

### STUDY DESIGN

- Selection Criteria

[1] Inclusion Criteria

- a) Individuals of either sex and of first MBBS students willing to participate in study
- b) Healthy individuals without any known disease or history of any medication or drug ,or tobacco or alcohol. Student were instructed to avoid caffeinated drink on the day of study

[2] Exclusion Criteria.

- a) History of any medication or drug ,or tobacco. Student were can not avoid caffeinated drink i.e. tea coffee on the day of study
- b) Unable to cooperate to undergo the study design.

The single-letter cancellation task (SLCT) consists of a sheet of 22 rows  $\times$  14 columns of randomly arranged letters of the alphabet. Subjects are told to cancel target letter at a time. It is also suggested that, according to their own choice, they follow horizontal, paths on the test sheet. They are told to cancel as many target letters as possible in the test time of 90 secs. Test was supervised with a standard stopwatch. . The total number of correct responses the time taken to complete the task was recorded for every subject. Scoring for test counts total correct cancellations attempted. Mean Score was obtained among both the groups and compared by students t –test with the help of statistician .

### Results :

Study documented the fact that there group n1 =25 Normal sleep group [Male 19,female 6] performed significantly better than Group n2 =23 subjects sleep deprived group[Male 19,female4].

The difference was statistically significant [ $P \leq 0.001$ ]

Statistical test : standard manual t –test was done .

Group n1 25 students Normal sleep group (19 males, 6 females;) of mean age 18 ±1.43

,and group n2 sleep deprived group (19 males, 4 females;) of mean age 18 ±1.53 years group n=23 (statistically insignificant )

Mean score n1= 65.01 ,n2=59.91

95% **CI**: 5.25 to 10.92

t=5.7311

DF=46

St error of difference :1.409

**Table-1: Impact of sleep deprivation on SLCT score**

	Group n1	Group n2
	Normal sleep[6-8 hours]	Sleep deprived[2-4 hours]
Mean score	65.01	59.91
Standard deviation	4.92	4.82
SEM	0.98	1.01
N	25	23

P<0.001

Amongst the group n2 sleep deprived group male were significantly more than females.

**DISCUSSION:**

Out of 150 student 23 students [ 15.33 %] preferred sleep deprivation method to carry out additional stress of examination while remaining students preferred to sleep normally .The study documented the fact that sleep deprivation is associated with poor out come with SLCT means decreased attention function . Similar result was observed with study of Dixit et al . More than females students preferred sleep deprivation in nights in the hope of securing better score in examination . But SLCT show inferior

performance with sleep deprivation compared to normal sleep group .so deprivation of sleep can compromise their performance examination also. But due to our limitation, study we did not published examination performance correlation. The study evaluated the performance by SLCT and Reactivity by simple paper-pencil tasks in order to address this issue .The SLCT with paper-pencil tasks are easy to administer and inexpensive, suitable for any operational settings .The validity is tested in many experimental set up. *Sleep deprivation brings about decreased score and increase errors decrease in vigilance and performance in SLCL. This suggests that this can lead to unfavorable outcomes in examination performance.* Vigilance tasks with SLCT .*The effect of sleep fragmentation on cognitive abilities is also studied and result suggests that generally sleep fragmentation has less pronounced than effects of sleep deprivation and effects are at least partly mediated by decreased arousal and increased sleep pressure leading to inconsistent performance ( poor attention tests).* Insufficient sleep leads to a general slowing of response speed and increased variability in performance, particularly for simple measures of alertness, attention and vigilance. Emerging evidence suggests that some aspects of higher level cognitive capacities remain degraded by sleep deprivation despite restoration of alertness and vigilance with stimulant countermeasures, suggesting that sleep loss may affect specific cognitive systems above and beyond the effects produced by global cognitive declines or impaired attention processes.

**CONCLUSION.** The study documented the fact that sleep deprivation is associated with poor out come with SLCT means decreased attention function . The results indicated that Group n2 23 subjects [sleep deprived group], performed was inferior to group n1 25 Normal sleep group. This suggest that attention, concentration and visual signal interpretation, speed, spatial orientation was significantly affected by sleep deprivation. Medical college policies and class schedules that encourage healthy and adequate sleep could have a positive impact on attention and concentration in academic sessions and evaluation period, learning, and health of medical college students. This also promote abstinence of misuse of drugs, tobacco and caffeine . Future research to investigate effective and feasible interventions, which disseminate both sleep

knowledge and encouragement of healthy sleep habits sleep hygiene's to medical college students in a time and cost effective manner, is today priority.

Limitation and Scope of the study:

Increasing number of subjects, Including subjects from different faculties and age groups, testing impact of other factor like physical and mental stress on attention parameters, assessing electrical i.e EEG and biochemical parameters and endocrine parameter of sleep,more helpful research may include trying to better ascertain the contributions of other neural systems that may impact on vigilance, including stress, motivation, and novelty including objective parameters sleep duration.

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**13 Message World Health Day 2015 – FOOD SAFETY:  
From farm plat to food plat  
7 April 2015 - World Health Day**

Campaign at a glance Every year, the World Health Organization selects a priority area of global public health concern as the theme for World Health Day, which falls on 7 April, the birthday of the Organization. The theme for World Health Day 2015 will be Food Safety, a theme of high relevance to all people on the planet, and multiple stakeholders, including government, civil society, the private sector, and intergovernmental agencies. Safe food underpins but is distinct from food security. Food safety is an area of public health action to protect consumers from the risks of food poisoning and foodborne diseases, acute or chronic. Unsafe food can lead to a range of health problems: diarrhoeal disease, viral disease (the first Ebola cases were linked to contaminated bush meat); reproductive and developmental problems, cancers. Food safety is thus a prerequisite for food security. New threats to food safety are constantly emerging. Changes in food production, distribution and consumption (i.e. intensive agriculture, globalization of food trade, mass catering and street food); changes to the environment; new and emerging bacteria and toxins; antimicrobial resistance—all increase the risk that food becomes contaminated. Increases in travel and trade enhance the likelihood that contamination can spread. The World Health Organization helps and encourages countries to prevent, detect and respond to foodborne disease outbreaks—in line with the Codex Alimentarius, a collection of international food standards, guidelines and codes of practice covering all the main foods. Recognising that food safety is a cross-cutting issue and shared

**Background**

Unsafe food is linked to the deaths of an estimated 2 million people annually – including many children. Food containing harmful bacteria, viruses, parasites or chemical substances is responsible for more than 200 diseases, ranging from diarrhoea to cancers.

New threats to food safety are constantly emerging. Changes in food production, distribution and consumption; changes to the environment; new and emerging pathogens; antimicrobial resistance - all pose challenges to national food safety systems. Increases in travel and trade enhance the likelihood that contamination can spread internationally.

**The topic for World Health Day 2015 is food safety**

As our food supply becomes increasingly globalized, the need to strengthen food safety systems in and between all countries is becoming more and more evident. That

is why the WHO is promoting efforts to improve food safety, from farm to plate (and everywhere in between) on World Health Day, 7 April 2015.

WHO helps countries prevent, detect and respond to foodborne disease outbreaks - in line with the *Codex Alimentarius*, a collection of international food standards, guidelines and codes of practice covering all the main foods and processes. Together with the UN Food and Agriculture Organization (FAO), WHO alerts countries to food safety emergencies through an international information network.

### **Five keys to safer food**

Food safety is a shared responsibility. It is important to work all along the food production chain – from farmers and manufacturers to vendors and consumers. For example, WHO's *Five keys to safer food* offer practical guidance to vendors and consumers for handling and preparing food:

- Key 1: Keep clean
- Key 2: Separate raw and cooked food
- Key 3: Cook food thoroughly
- Key 4: Keep food at safe temperatures
- Key 5: Use safe water and raw materials.

World Health Day 2015 is an opportunity to alert people working in different government sectors, farmers, manufacturers, retailers, health practitioners – as well as consumers – about the importance of food safety, and the part each can play in ensuring that everyone can feel confident that the food on their plate is safe to eat.

With thanks Web site World Health Organization, South-East Asia Regional Office

## **14 New MEDICAL GADGETS**

### **A] An electronic cigarette e cigarette**

personal vaporizer (PV) or electronic nicotine delivery system (ENDS) is a battery-powered vaporizer that simulates the feeling of smoking. They are often cylindrical, with many variations. Some e-cigarettes look like traditional cigarettes, but others do not.<sup>[3]</sup> There are disposable or reusable versions. The user inhales an aerosol, commonly called vapor, rather than cigarette smoke. E-cigarettes typically have a heating element that atomizes a liquid solution known as e-liquid. E-liquids usually contain propylene glycol, glycerin, nicotine, and flavorings. E-liquids are also sold without propylene glycol, without nicotine, or without flavors.

The nicotine inside the cartridges is addictive. When you stop using it, you can get withdrawal symptoms including feeling irritable, depressed, restless and anxious. It can be dangerous for people with heart problems. It may also harm your arteries over time. So far, evidence suggests that e-cigarettes may be safer than regular cigarettes. The biggest danger from tobacco is the smoke, and e-cigarettes don't burn. Tests show the levels of dangerous chemicals they give off are a fraction of what you'd get from a real

cigarette. But what's in them can vary. "E-cigarettes may be less harmful than cigarettes," Drummond says. "But we still don't know enough about their long-term risks or the effects of second hand exposure."

#### Pro and Con

E-cigarettes have triggered a fierce debate among health experts who share the same goal -- reducing the disease and death caused by tobacco. But they disagree about whether e-cigarettes make the problem better or worse.

The FDA has proposed new regulations that would extend the agency's authority over many tobacco products, including e-cigarettes.

A minimum age requirement is among the proposed regulations.

Opponents say that because nicotine is addictive, e-cigarettes could be a "gateway drug," leading nonsmokers and kids to use tobacco. They also worry that manufacturers -- with huge advertising budgets and celebrity endorsements -- could make smoking popular again. That would roll back decades of progress in getting people to quit or never start smoking.

#### **BJ CENTRAL ARTERIOVENOUS ANASTOMOSIS for the treatment of patients with uncontrolled hypertension**

Hypertension contributes to cardiovascular morbidity and mortality.

Ever since Medtronic announced less than stellar news about the effectiveness of its renal denervation system in a clinical trial, it's been a bit gloomy for those hoping to get off blood pressure drugs once and for all. Now there's new hope that rests in a small implant from **Rox Medical** (San Clemente, CA) that has shown to work effectively in a trial organized among a number of European Centres of Hypertension Excellence.

The Coupler device is implanted into the upper thigh where it is used to create a connection, a sort of fistula, between the iliac artery and iliac vein, allowing some blood to flow between the two. The cath lab procedure takes about forty minutes to complete and doesn't require sedation, a bit of local anesthetic being sufficient. Once implanted, the device helps reduce peripheral vascular resistance and lead to overall lowering of blood pressure. In the study of 83 patients, there was a reduction of 26.9 mm Hg in hypertension in those receiving the Coupler, while the control group only had a 3.7 mm Hg reduction. Interestingly, the device was shown to benefit even those that tried out renal denervation previously with little luck.

#### **RCT and FDA approval is under way for both the gadgets**

**Conference on 11<sup>th</sup> October 2015**  
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**A]Date : 11/10/15**

**Time :8-30 AM to 6-30 PM**

**Areas to be covered:**

**Inauguration function**

**Dean madam Dr Dipti Shah & others president ,secretaries...**

**Life on artificial Lung ECMO**

**Life on artificial Ventilation**

**Life on artificial pace makers**

**Life on artificial Dialysis machine**

**Life on artificial catheters , tubes and wires in GIT**

**Life on artificial catheters , tubes and wires in Reproductive system**

**Life on artificial joints, bone and muscle**

**Life on artificial catheters, tubes and wires in Renal system**

**Life on artificial aesthetic and implant**

**Life on artificial dentistry**

**And many more**