

*Material  
and  
Methods*

## **MATERIALS AND METHODS**

The present work pertaining to dynamic lung functions and fetal ultrasound determination in pregnant women and their perinatal outcome was carried out jointly in the Department of Physiology, Medical College, Baroda and Department of Obstetrics and Gynecology, Shree Sayaji General Hospital, Baroda.

The subjects were the pregnant women attending the antenatal clinic of obstetrics and gynaecology. All women attending the antenatal clinic on Mondays, Wednesdays and Fridays were selected for the study and were explained the purpose and importance of the same. Only those who were motivated enough to give their consent readily were recruited in the study. Total subjects thus recruited were 197.

Details of their vital data, the present and past history and family history regarding the general, medical, surgical and gynecological history were inquired and recorded in the proforma. Routine blood and urine examinations were done. Both primigravida and multigravida with no overt clinical evidence of malnutrition and Hb > 8 gm% were included in this study. Subjects on the basis of proforma were grouped into Group I-P and Group II-P. Group I-P comprised of normal healthy, non- smoking pregnant subjects. Group II-P comprised of subjects who were clinically stable during their present pregnancy but had a previous history of respiratory illness for at least six months before conception. As per history they either had chronic cough of about a period of two to three months mostly due to common cold, or previous episodes of bronchial asthma or upper respiratory tract infections or TB, etc. Subjects with history of smoking or passive smoke exposure were also included in the present study under Group II-P. The subjects with history of smoking bidis  $\geq 5$ /day for more than three years and those with passive smoke

exposure of more than two hours each day, either at work place or at home were considered in this group. The pregnant women having acute cardiac diseases, renal diseases, preeclampsia, eclampsia, anemia (Hb < 8 gm %) or any other significant illness during last two years were excluded. Those subjects who could not execute the procedure of lung function determination and those who did not show up on the actual test day or did not deliver the baby at SSGH or did not turn up for the consequent follow up for varied reasons were also excluded from the present study. Eventually out of 197 subjects recruited 47 were excluded.

Based on the above criterion, the present study finally focused on 150 pregnant subjects. All the subjects belonged to lower socioeconomic class had more or less similar height, weight and age group (Table 1). All patient continued their daily routine work and diet with no instructions or restrictions. The same subjects in their 6-8 weeks of postpartum served as the control subjects (Group I-PP and Group II-PP).

The duration of pregnancy as noted through self reported last menstrual period (LMP), was confirmed on clinical examination by the consulting Obstetrician and was correlated to the gestational age as determined by ultrasound conducted twice during their pregnancy, first at 12 weeks and next at 32 weeks gestation.

The experiment was designed in the following way:

1. First day – Trial and training on expirograph.
2. Second day – Actual test (FVC determination)
3. Third day – Ultrasonography and pulse-oximetry.
4. Postnatal perinatal outcome data collection
5. Postpartum (6–8 weeks) FVC determination and pulse-oximetry.

### *First day – Trial and training.*

Four to five subjects in their third trimester of gestation (28–34 weeks), recruited on each scheduled day of the week were brought to the respiratory laboratory setup in the Department of Physiology, Medical College, Baroda. The expirograph was shown and the procedure and duration of the experiment with the instrument was explained to them. When the spirometric test is proposed even a healthy person often experiences fear and nervousness, which may lead to errors in the results of the test, so in order to reduce such anxiety, the operation of the instrument and procedure of the test was briefly explained, clearly pointed out that it is merely a matter of breathing ordinary air from the instrument and that it involves no danger or discomfort of any kind.

They were then given trial breathing through mouthpiece two or three times with nose clipped to get accustomed to the instrument. Whenever one subject was given trial breathing, others would observe. Thus each subject was demonstrated and trained to perform the test and its proper execution was demanded on each attempt (Kory et al, 1963; Lal et al, 1964).

The subjects were instructed to report to the respiratory laboratory setup at 8 o'clock next day morning, on an empty stomach having fasted since 8 o'clock the previous night, without any physical exertion.

### *Second day – Actual test.*

On arrival to the laboratory setup the next day, the subject was asked to take rest for thirty minutes. Height, weight, pulse, blood pressure, respiratory rate and oral temperature were then noted and

minimum three forced vital capacity graphs were recorded. All these parameters were recorded by standard methods.

The forced vital capacity was determined by using a Godart NV Expirograph (Holland) by the researcher. The instrument used is a 9 liters, water sealed expirograph connected to a corrugated rubber tube holding a disposable mouthpiece that is to be placed in subjects mouth. The bell of the expirograph is connected to a string ink pointer for graphical recordings. The recordings were obtained on a graph paper on a moving drum at a given speed by an electric motor.

The subject was instructed to perform forced vital capacity maneuver in standing position as recommended by the American Thoracic Society. The subject was asked to hold the rubber tube in her hand with the mouthpiece near her mouth and nose-clip firmly applied. Then she was asked to take deep, slow maximum inspiration of room air through the mouth and holding on to the breath was promptly made to place the mouth piece in the mouth, held tightly between the lips, without the loss of air to the exterior. Then the subjects was asked to expire out forcefully, as fast as and as long as possible into the mouthpiece. To make it reproducible, on each attempt the subject was encouraged to make a maximum effort. A series of three determinations were made, with a rest of 10 minutes between each and the highest reading of these was taken as the measured forced vital capacity (Dawson, 1965; Rosner et al, 1965; Kemm & Kamburoff, 1970). The instantaneous and dynamic pulmonary functions were then calculated manually from the obtained FVC graph.

On standardization, the volume represented on Y – axis of the standard graph paper was calibrated to be 300 ml per centimeter of vertical movement of the pointer. Time calibration denoted on X – axis of the graph paper was 0.05 sec/mm when the speed of expirograph

was adjusted to 1200 mm/min. All the values thus obtained were interpreted at body temperature and pressure saturated with water vapor (BTPS).

The subjects were then relieved from the laboratory with the instructions to report on next day afternoon between 3 to 5 pm, to the ultrasound room, Department of Obstetric & Gynecology, SSGH, Baroda.

### *Computations*

a) *Forced vital capacity* (FVC in liters): This is the volume of air which can be *forcibly* and *maximally* exhaled out of the lungs after taking maximal inspiration or the deepest possible breath. This pulmonary function test value is critically important in the diagnosis of obstructive and restrictive pulmonary diseases.

b) *Forced expiratory volume in one second* (FEV<sub>1</sub> in liters): This is the volume of air that can be forcibly exhaled from the lungs in the first second of a forced expiratory maneuver.

c) *Forced expiratory volume in one second as a percentage of FVC* (FEV<sub>1</sub>%): This value is the ratio of FEV<sub>1</sub> to FVC and indicates what percentage of the total FVC was expelled from the lungs during the first second of forced exhalation.

d) *Maximum instantaneous forced expiratory flow* (Vmax/FEF in liters/sec): Forced expiratory flow is a measure of the flow rate of air expired from the lungs at a particular instance of FVC. Here, the FVC expiratory curve is divided into quartiles and thus it is determined for each quartile that is Vmax<sub>25%</sub>, Vmax<sub>50%</sub> and Vmax<sub>75%</sub>.

Manually, these were determined by locating each quartile (point representation) on the volume axis of the FVC curve and then

draw a tangent through each of these points. Since it is expressed in liters per second, time measure is taken as constant that is one second from the start of expiration that is 2 cm or 20 mm of the horizontal axis of the graph paper. The slope of this tangent over time represents the rate of airflow at a particular instant (quartile) of FVC.

e) *Forced expiratory flow 200 – 1200 cc* ( $FEF_{0.2-1.2}$  in liters/sec): This is the maximum flow rate measured from 0.2 to 1.2 L of the volume axis of FVC curve. This was determined by locating points each representing end of 0.2 L and 1.2 L of expiration on the FVC curve and passing a straight line through both these points. The time measure kept constant, the slope of this line represents an average flow rate between these two volumes.

f) *Forced expiratory flow between 25 and 75 percent of forced vital capacity* ( $FEF_{25-75\%}$  in liters/second): This measurement describes the amount of air expelled from the lungs during the middle two quarters of the volume segment of FVC curve so is also termed as maximal mid expiratory flow rate. This is most effort independent portion of the curve and thus can indicate obstruction of varied degrees.

This was determined by locating points on the FVC curve corresponding to 25% and 75% of FVC, and passing a straight line through these points. A slope of this line represents the average rate of flow over the mid portion of FVC.

g) *Forced expiratory flow between 75% and 85% of forced vital capacity* ( $FEF_{75-85\%}$  in liters/sec): This is also termed as maximal end expiratory flow rate. Locating points on the volume time curve corresponding to 75 percent and 85 percent of FVC, and then passing a straight line through these points can determine FEF. A slope of this line represents the average rate of airflow over the end portion of FVC.

### *Third day: Ultrasonography (USG) and Pulse - Oximetry:*

#### *Ultrasonography*

Ultrasound scan was performed on the subjects by same trained Obstetrician who had earlier measured crown to rump length (Robinson formula) in all these subjects for confirmation of the gestational age of 12 weeks, using the same instrument to avoid inter-observer and inter-instrumental differences and errors.

Linear measurements were performed with the help of a distance cursor, while circumference measurements were performed using elliptical cursor. The instrument used is a Phillips, Sono Diagnost 100, Netherland, a B mode key and 3.5 M Hz HD (high definition) curved array probe.

The fetal measurement of biparietal diameter (BPD), head circumference (HC), abdomen circumference (AC) and femur length (FL) were made, while the ratios FL/BPD, FL/AC and HC/AC were obtained from the computer through predesigned calculations. The gestational age and fetal weight was estimated from the above parameters and ratios using computed formulae.

(1) Biparietal diameter (BPD): Three Polaroid pictures of the fetal head were taken with falx - cerebri located centrally. A centimeter scale was superimposed on each picture. The fetal head was measured with calipers from the outer aspect of the head to the inner aspect of the contralateral side of the head. The average of the three measurements was used as a BPD.

The midline falx echo should be equidistant from both skull tables and third ventricle. Both anterior horns of the lateral ventricles should be seen in the same plane. BPD was measured in this plane,

from inner table on one side to the outer table of skull on the other (Campbell formula). BPD was accurate within the range of  $\pm 2$  weeks nearing term.

(ii) Head circumference (HC): Head circumference was also read at the same level by calculating from outer to outer measurements of the short and long axis of the fetal head (Campbell formula).

(iii) Abdomen circumference (AC): The abdomen circumference measurement (Campbell formula) was made from a transverse section of the fetal abdomen at the level of left portal vein (portal umbilical venous complex). Two diameters were measured at right angles using the formula  $(D1 + D2) \times 1.57$ .

(iv) Femur length (FL): Femur length was measured between the two heads of femur bone (Hansmann formula).

The ratio analysis was conducted with the aid of the user ratio, which is as following:

Ratios	User ratio	Gestational age
HC / AC	0.89 - 1.31	12 - 40 weeks
FL / AC	20% - 24%	21 - 40 weeks
FL / BPD	71% - 87%	23 - 40 weeks

#### Pulse Oximetry:

After the ultrasound scanning the subjects were made to relax mentally and physically in the waiting room outside the obstetric operation theatre. The pulse-oximeter was brought to the waiting room and was placed next to the patient. The nail of the subject's forefinger was cleaned using acetone for removing nail polish whenever required and then with spirit to disinfect.

A portable DATEX-OHMEDA made pulse oximeter was used to measure the oxygen – hemoglobin saturation. The probe was then attached over the fingertip and a continuous pulse waveform displayed visually was studied. When a steady continuous waveform is displayed, the digital reading of oxygen saturation is noted along with the pulse rate. Three readings at an interval of five minutes were taken and the average was considered.

*Perinatal outcome data collection:*

The perinatal outcome data were collected retrospectively from the standard prenatal, labor, delivery and postpartum hospital records. The following neonatal outcome parameters were evaluated as dependent variable (i) Neonatal birth – weight (continuous variable), (ii) Height/Length from vertex to heel in cms. (iii) Low birth weight (LBW) infants (< 2500 gms); ponderal index (PI):  $PI = B/L^3 \times 100$  where B is birth weight in grams and L is length in centimeters.  $PI < 2.2$ , is suggestive of intrauterine growth retardation (IUGR). (iv). Preterm births: Delivery before 38 weeks gestation. The chest circumference and head circumference were also recorded. Placental weight was noted along with other maternal outcomes.

Daily visits to the Obstetrics and Gynecology ward enabled the researcher to visit each subject personally and confirm the neonatal data as well as to motivate her to visit the respiratory laboratory setup once again at their 6-8 weeks postpartum, at 8 o'clock in the morning, having fasted since 8 o'clock the previous night.

### *Postpartum (6 – 8 weeks)–FVC determination and Pulse-oximetry:*

Adhering to the previously adopted conditions, methodology and instruments, three FVC records and oxygen saturation records were obtained.

These postpartum data served as the control data for the same subjects.

### *Statistical analysis:*

Statistically the outcomes were measured for different groups as mean  $\pm$  SD. The differences were calculated by using unpaired student's 't' test, the results will be considered as significant at  $P < 0.05$ .