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OFFICE BEARERS OF IMA (HQS)

Editorial

National Doctor's Day

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National doctor's Day is observed to thank Physicians and doctors for their dedicated service to patients. After all they have looked after persons in their worst times. National Doctor's Day is an opportunity to the people to express their gratitude towards Doctors. Doctor's Day is celebrated on different dates in different countries across the world. Several government and non government health care organisations celebrate this day. Doctors play an important role in human life. National Doctor's Day is first celebrated in July 1991. It is necessary to a raise awareness about the roles, importance, and responsibilities of doctors and to promote medical profession.

It is truly none can see god on earth. Doctor is considered like god as they can cure and give the human a life to live in a better ways. First time the Doctor's Day was observed in March 1933 in the US state of Georgia. The day was celebrated that time by sending cards to physicians and placing flowers on the graves of the dead doctors.

National Doctor's Day in observed every year on 1st July in India to honour the legendary physician and second chief minister of West Bengal Dr. Bidhan Chandra Roy. On this day people acknowledge the contribution of doctor's humane service to mankind. The 1st July is the birth and death anniversary of Dr. Bidhan Chandra Roy.

Dr. Bidhan Chandra Roy was born on 1st July 1882 and also died on the same day in 1962. On 4th February in 1961 he was honoured with the Indian's highest civilian award Bharat Ratna. Dr. Bidhan Chandra Roy was a highly respected physician and a renowned freedom fighter. He was the second chief Minister of Bengal and remained about 14 years in his post that is from 1948 until his death in 1962. He is also considered as the great architect of West Bengal. Five cities in West Bengal was founded by him namely Durgapur, Bidhannagar, Ashoke Nagar, Kalyani and Habra. He was also a member of Brahmo Jamaj. In the Medical College of Calcutta he was the aluminums of the university of Calcutta. In his memory the union Government had also instituted an award as Dr. B.C. Roy award every year. He played an instrumental role in the establishment of Indian Medical Association (IMA), and also in the establishment of Medical Council of India. (MCI).

National Doctor's Day, 2019 : — The theme of National Doctor's Day 2019 is zero tolerance to violence against doctors and clinical establishment. Every year the theme was announced by the Indian Medical Association. This theme will raise awareness about the violence happening with the doctors across India. The weak of July 1st to 8th July will also be celebrated as 'Safe Fraternity Week'.

National Doctor's Day celebration across the world : — Since several years National Doctor's Day is celebrated throughout the world by Government and Non government health care organization to get familiar with the doctor's contributions Health care organizations staffs organizes several events and activities on the day.

In some nations the Doctor's Day is ranked as a holiday. Although supposed to be celebrated by patients and benefactors of the health care industry, it is usually celebrated by health care organizations. Staff may organise a lunch for doctors to present the physicians with tokens of recognisation. Historically card or red carnation may be sent to the physicians and their spouses, along with flowers being placed on graves of deceased physicians.

Some Celebrating Nations : —

Kuwait : In Kuwait the national Doctor's Day in celebrated on 3rd of March. The idea of celebration come from the Kuwait business woman Zahra Suliaman Al-Moussawi. The date was chosen due to being the birthday of Dr. Sundal Al-Mazidi, her daughter.

Brazil : In Brazil, National Doctor's Day is celebrated as a holiday on October 18th the day on which the catholic Church celebrate the birthday of saint Luke. According to the church tradition the apposite and evangelist saint Luke was a doctor.

Canada : National Doctor's Day in celebrated in Canada on 1st May. All Ontorians can participate by recognizing the doctors via Social media by tweeting using the hastag 'love my MD'.

Cuba : In cuba national Doctor's Day is celebrated as a holiday on December 3rd to commemorate the birth day of Carlos Juan Firday who was a Cuban physician and scientist recognized as a pioneer in yellow fever research.

India : In India National Doctor's Day in celebrated on 1st July on the birth and death day of legendary Physician Dr. Bidhan Chandra Roy.

Iran: In Iran, Avicenna's birthday 23rd August is Commemorated as the national day for doctors.

Malaysia : Here Doctor's Day is celebrated on the 10th of October every year. It was first launched by the Federation of private Medical practioners Association, Malaysia in 2014.

United States: In United states national Doctor's Day in celebrated on March 30 every year. The idea came from Eudora brown Almont, wife of Dr. Chavles Almont and the date chosen was the anniversary of the first use of the general anesthesia in surgery.

Vietnam : Vietnam founded Doctor's Day on February 28, 1955. The day is celebrated on 27th February or sometimes closest to this date.

Nepal : Nepal celebrates Nepal Doctor's Day on Nepali date Falgun 20 i.e. 4th March. Since the establishment of Nepal Medical Association, Nepal has organised this day every year. The doctor patient communication, Clinical treatment and community based health

promotion and care discussed.

National Doctor's Day Celebrations : — Since several years National Doctor's Day is celebrated by the Government and non-government health care organizations to get familiar with the doctor's contributions. Health care organization staff organizes several events and activities on this day. For grant celebration on doctor's day rotary club of North Calcutta and North East Calcutta social and welfare organization organised big events annually.

Free medical check up camps are organised at various health care organizations to promote quality medical services free of cost among public. National medical services by the doctors are also promoted. Various discussion programmes are organised across the country to make people aware about health check up, prevention, diagnosis, proper treatment of the disease etc.

General screening test camps are also organised to assess the health status, health counseling, health nutrition talks and chronic diseases awareness among the people and senior citizens. Various activities are also organized to make people aware about the priceless roles a doctors in every one lives like free blood tests, random blood sugar test, ECG, EEG, Blood pressure check up etc.

Several activities at schools and college levels are also organised to encourage youth to choose and dedicatedly follow the medical profession.

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Review Article

Mobile phone usage pattern among undergraduate medical students in a Medical College of West Bengal, India

Indranil Saha[1], Tapas Kumar Som[2], Sreemedha Choudhury[3], Gautam Ghose[4], Bobby Paul[5]

One of the most prominent and widespread product of technology in today's world is the 'Mobile phone'. Although a boon for better communication; there have been endless controversies over frequent use of mobile phones. The study was conducted to find out the pattern of mobile phone usage among undergraduate medical students and to determine any hazards faced by them and their involvement with mobile phones. It was a cross-sectional study conducted at IQ City Medical College, Durgapur, District Burdwan, West Bengal, India during July to August 2015 among 252 undergraduate medical students. Statistical Package for Social Sciences (SPSS) software (version 19.0) was used for analysis. Maximum students used their mobile phones in class (42.5%). About 67.1% were aware of hazards related to mobile phone usage. The most commonly experienced symptom was headache (61.5%), followed by ringxiety (34.7%). Half of the subjects could not live without phone for a single day. Dependence on mobile phone and its hazards have become an issue nowadays due to the multiplicity of its functions. Rules and regulations need to be placed in time regarding its use is the need of the hour.

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Key words **: Mobile phone use, smartphone, headache, ringxiety, medical students.**

One of the most prominent and widespread product of technology in today's world is the 'Mobile phone'. Gone are the days when phones were considered a rich man's luxury; mobile phones have reached people of all ages and economic status. Reduction in cost of handsets, communication, smaller size etc. has contributed to the surprisingly rapid adoption rate of mobile phones by the people, especially the young generation[1].

Most of the mobile phones nowadays are addressed as 'smartphone', as they offer more advanced computing power and connectivity than any regular mobile phone. With a smartphone, the user can do multitasking on the go like- make voice calls, video calls, SMS and MMS; it's like a laptop integrated with a phone. Smartphones have thus been aptly repositioned as a "new information medium"[2].

Although a boon for better communication; there have been endless arguments and counter researches over frequent use of mobile phones and their long term effects due to low powered radiofrequency transmission[3].

One of the major bulks of the subscription base of mobile phone users is comprised of college students. They defend their usage by citing various uses of the mobiles; the most common being searching infotainment sites for their curriculum based works. Mobile phones satisfy the need for individualisation and yet also signify being a part of a peer group[4].

In this background, the present study was conducted to find out the pattern of mobile phone usage among undergraduate medical students and to determine any hazards faced by them with excessive usage and their involvement with mobile phones.

Materials and Methods

The present study was an institutional based observational epidemiological study having a cross-sectional design conducted at IQ City Medical College situated in Durgapur, District Burdwan, West Bengal. This is a private medical college established in 2013, which enrols 150 students every year for MBBS course. The college is attached with a multispecialty hospital – Narayana Hrudayalaya Hospital. Study period was July to August 2015, and the study population comprised of senior most 2

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batches ie, 4th semester and 2nd semester batches of MBBS students both male and female, having mobile phone. The two batches comprised of 146 and 149 students respectively. Pretesting of the questionnaire was conducted upon 10 students: 5 students from each batch for pilot study. These 10 students were omitted from the final study. Thus altogether 285 ([146 + 149] – 10) students were approached for the final study. The students who did not submit the questionnaire or submitted almost incomplete questionnaire were excluded from the study. Finally analysis was done on 252 students with a response rate of 88.4%. No sampling was done and complete enumeration method was followed. Study tool was pre-designed and pre-tested structured self administered questionnaire. Students were approached after class hours and were briefed about the purpose of the study and were asked for informed written consent. The study was approved by Ethics Review Board (ERB) of the institute.

Operational definition: We classified the mobile phone usage in the class as follows: Yes: When mobile phone is used every day during class hours. No: When mobile is never used during class hours. Rarely: When mobile phone is used during class hours but less than 2 days in a week. Prolonged use of mobile phone: When mobile phone was used for 2 hours or more in a day, was termed as prolonged mobile phone usage. Mobile phone hazards known: A checklist of hazards of mobile phone usage after extensive literature review was prepared and if the student correctly answered any one of them, then it was taken as "yes" hazard known. Ringxiety: The phenomenon of mistakenly thinking that mobile phone is ringing / vibrating[5]. Nomophobia: Nomophobia was defined as fear of being without mobile phone[5].

Collected data were compiled on Microsoft Excel worksheet. Categorical data were expressed as proportions. Statistical Package for Social Sciences (SPSS) software (version 19.0) was used for analysis.

Results

Out of 252 study subjects, highest number of participants was in the age group of 20 to 21 years, followed by 18 to 19 years (35.3%) and least number of subjects was in the age group of less than18 years. About, 53.6% were females and rest 46.4% were males; 46.5% of them were in the 2nd semester and 53.5% were in 4th semester. Majority i.e. 81.4% were hostelites, 85.7% belonged from urban area, and 88.1% were Hindus. Highest numbers of respondents (92.8%) were in Upper Class as per modified BG Prasad socio-economic status scale.

All the students had mobile phone. The maximum number of handsets was in the price range of Rs. 10001-Rs. 15000 (25.7%), followed by more than Rs. 20001 (25.3%); while least number of students (8.4%) had mobile phone in the price range of Rs 1000-5000. About, 96.6% of the subjects owned smartphones.

The most pursued purpose for buying mobile phone was 'Feel it's a necessity in today's life' (75%) followed by 'Connectivity with near and dear ones' (44.8%), while 3.9% students cited 'Other reasons', like taking pictures, recreational purposes etc. Most of the subjects ie, 73.1% were using mobile phones for more than 3 years while least numbers of respondents (1.5%) were using mobile phones for less than 1 year. Highest numbers of respondents (34.5%) had changed more than 3 mobile phone sets till date, while least numbers of respondents (9.1%) had changed 1 mobile phone set till now.

The most common answer about using mobile phone was 'Helps stay connected with near and dear ones' (86.9%), followed by makes life convenient (69.8%) and makes me feel safe (48.1%); while 6.3% students said 'Other reasons' (6.3%), like recreation in idle time, multitasking, educational purposes etc.

The most commonly done task on mobile phone was 'Calling family and relatives' (98.3%), followed by internet browsing (90.3%) and social networking (87.5%); while least was 'Other reasons' (12.4%), like photography, online shopping, navigation by GPS etc. The task on which maximum time spent was 'Social Networking' with a median value of 45 minutes, followed by internet browsing (40 minutes); while minimum time was spent on checking email with a median value of 10 minutes.

Regarding the amount of total recharge (including all costs) and other charges done on phone at a time, majority were under the category of Rs 201-400 (36.4%) and Rs 401-600 (19.2%). Regarding to internet expenditures on phone, majority came under the category of Rs. 101- 200 (41.7%), followed by Rs 201-300 (25.4%). About 0.8% subjects did not spend on internet.

Maximum students used their mobile phones in class (42.5%); and in contrast only 26.6% students did not use phone in class. Maximum number of subjects (76.4%) used mobiles in class to surf the internet, followed by texting or chatting, which comprised of 75.4%. The most common purpose of browsing was 'Recreational activities' and 'Social networking' (93.8% each), and less common was 'Information, news and general affairs' (50.6%) (Table 1). Maximum ie, 45.8% subjects did not use mobile phones while driving (45.7%); while least number of subjects use mobile phones while driving (3.6%).

About 67.1% were aware of mobile phone related hazards. The most commonly experienced symptom was

Table 1 — *Distribution of the study subjects according to whether mobile phone used in class*

Responses	Frequency	Percentage
Mobile phone used in class (n = 249*) :		
Yes	106	42.5%
No	66	26.6%
Rarely	77	30.9%
Activities done during class (n = 106) :		
Receive/ make calls	20	18.8%
Texting/ chatting	80	75.4%
Listening music/ Watching Videos	30	28.3%
Surfing internet	81	76.4%
Playing games	59	55.7%
To check time	72	67.9%
Others	9	8.4%
Purpose for browsing internet (n = 81**)		
Education related	71	87.6%
Information, news and General affairs	41	50.6%
Updates and apps	53	65.4%
Recreation (music,video,movies,games etc)	76	93.8%
Social Networking	76	93.8%
Online shopping and Banking	42	51.8%

*3 respondents did not share their answers
**Multiple answers were recorded

headache (61.9%), followed by ringxiety (34.9%), nomophobia (17.1%) and dizziness (15.3%) (Table 2). In 86.8% of the respondents kept their cell phones off at night; in contrast 13.2% did not switch off mobile phone at night.

Half of the respondents said they could live without phones for a day; while the remaining half of the subjects could not live without phone for a single day. Maximum number of respondents (81.9%) stated the reason to be the need to stay connected with near and dear ones and the least (8.1%) said the reason as to feel addicted to mobile phones and have to keep it near (Table 3).

Discussion

Mobile phone is one of the greatest inventions in today's time. Although, it is extremely essential as a tool for communication and interpersonal interaction, but at the same time it has been criticised due to an increased risk in its problematic use in the recent times along with its hazards. In this background, the present study was conducted to find out the pattern of mobile phone usage among undergraduate medical students and to determine any hazards faced by them with excessive usage and their involvement with mobile phones.

Table 2 — *Distribution of the study subjects according to if any hazard related to mobile phones known or not*

Variables	Frequency	Percentage
Hazards known (n=243*)		
Yes	163	67.1%
No	80	32.9%
Symptoms experienced after prolonged mobile phone usage (n=163**) :		
Headache	101	61.9%
Dizziness	25	15.3%
Vomiting	7	4.2%
Ringxiety	57	34.9%
Nomophobia	28	17.1%
Any other	3	1.8%

*9 students did not share their answers
**Rest did not experience any symptoms; multiple answers were recorded

Table 3 — *Distribution of the study subjects according to involvement with mobile phone*

Involvement with phone	Frequency	Percentage
Stay without phone (n = 246*) :		
Yes	123	50%
No	123	50%
Reason if can't stay without mobile (n=111**) :		
Stay connected with near and dear ones and feel secure in case of emergencies.	91	81.9%
Dependent on mobile phone for various tasks, even basic chores.	13	11.7%
Feel addicted to using mobile phone, have to use it or keep it near.	9	8.1%
Recreation and feel updated with outside world	26	23.4%

*6 respondents did not respond
**Out of 123 respondents 12 respondents did not respond to this question and the rest responded that they could stay without phones for a day. Multiple responses were recorded.

Present study was a questionnaire based study, which was pre-designed with the help of all available literatures regarding mobile phone usage. Again it was pre-tested beforehand in the same settings; and same diagnostic criteria were applied for all the participants. Thus it is least likely to have introduced measurement bias in this study. About 11.6% students were non responders. Usually non responder bias arises from responders due to differences in demographic, socioeconomic, cultural, lifestyle and medical characteristics. Since, they more or less belonged from same socio-cultural backgrounds and are in same cohort presently, this type of bias is also very unlikely to happen in this situation.

The present study revealed that the use of mobile phones was almost universal, as also supported by Subba SH *et al*[5]. This implies that most of these students feel that mobile phones are very essential in today's life and hence it's a must to have one cell phone. The main purpose behind buying a cell phone among the subjects was connectivity with near and dear ones, similar to the findings of Subba SH *et al*, Zulkefly SN *et al*[5,6]. The reason could be due to the fact that, some portion of the students was from different parts of our country and their parents found it easier to keep in contact with their children through mobile phones. It is just a touch away from near and dear ones

and it also makes life convenient thorough different applications in smart phone like ticket booking, bill payment, readymade information, scanner, photo, games, music, news etc.

Majority of the respondents (73.1%) were using mobile phones for more than 3 years, which implies that most of the subjects had been using mobile phones for quite some time, mostly since high school.

Our study showed that most of the study subjects changed their cell phones within a span of 1.5-2 years. Changing mobiles frequently to get a better model / brand is considered as a stylish accessory and a status symbol and hence it creates a feeling of belongingness with peers as also found in a study by Fortunati L *et al*[7] Similar to present findings, Mittal *et al* also reported frequent changing of handsets among the students[8]. Also mobile phones offer major technological innovations, tools for which youngsters demonstrate a special inclination and skill[9]. The maximum number of handsets was in the price range of Rs10001-Rs15000 (25.7%). This implies that students invest a lot in buying and maintaining it. Total monthly cost of recharge on mobiles was maximally found to be under the category of Rs 201- 400 (36.4%), which is in accordance with Subba SH et al[5], who also found Rs300/- on an average. Datta S *et al*, Prajapati D *et al* also found monthly expenditure around Rs. 250-500/- per month[10,11]. In contrast, Zulkefly SN *et al* found this amount to be little higher, which amounted to about Rs800 among Malaysian college goers[6]. However, this difference could be due to the difference in purchasing power parity in two different countries.

Earlier one couldn't have imagined being able to do multitasking on a single device like-internet-browsing, gaming, texting, emailing, social networking, and phone calling. A smart-device (ie, smart-phone or tablet) allows these activities to be conducted anytime and anywhere and that too within a single device. In this study, 96.6% of the subjects owned smartphones, proportion much higher compared to study by Datta S *et al* in Kerala (77%). 10 Those who did not have smartphone, had much less mobile phone involvement than those having a smartphone as also supported by Harwood J *et al*[12].

Internet browsing is frequently done by students. The tasks are done mostly – recreation and social networking. Internet usage emerges as the main factor for mobile phone use in this study. So maybe this internet addiction is related to increased problematic mobile phone use, especially seen in smartphone users as also seen in the study done by Harwood J *et al*[12]. Similar findings have also been noted by Toda M et al, where lonely people used mobile more frequently that leads to problematic cell phone use[13].

In the present study, majority of the students (42.5%) used cell phones in class. This shows a disturbing trend among today's students. Students, especially medical undergraduates are expected to maintain complete discipline in class especially so as to become responsible heath care providers of tomorrow. Using mobile phones in class disturbs concentration and attention span and harms them. This result is almost similar to the results obtained in a study by Paul B *et al* (where 35.9% used mobiles in class)[14] and Subba *et al*[5]. However, Mahmoodabad *et al* found the proportion was bit higher (84%)[15]. This could mean that they are too dependent on mobiles and that they could not resist the temptation of using them even where they were prohibited. In previous studies, students used to receive calls in class and now in smartphone era, internet surfing has become the commonest activity.

In the present study, only 3.6% students used mobile phones while driving, which is quite alarming though the percentage is quite less. This finding was in fact quite contrary to the findings of Paul B *et al*, where majority of students preferred mobile phone use on road which is dangerous[14]. While, 18.6% students used phone while driving in a study by Mahmoodabad *et al*[15].

About 67.1% students were aware of mobile phone related hazards. Most stated radiation and cancer as the ill-effect, followed by cerebral problems, hearing problems and so on. Thus majority knew the harmful effect of using mobile phones excessively which is a positive finding similar to the findings of Paul B *et al*[16].

Most commonly experienced symptom in the present study was headache (61.9%), ringxiety (34.9%) and nomophobia (17.1%). Thus a majority of the subjects are experiencing hazards related to prolonged use which is disturbing to note as this may cause problems later on. Similar to present study, ringxiety was experienced by 34.6% students by Subba *et al*, which in turn hampered studies[5]. However, Datta S *et al* found ringxiety among 60.5% of medical students[10]. Cancer, specifically brain cancer, like glioma and its correlation with phone use, is also an ongoing investigation[16]. Hence, awareness against hazards of mobile phone use needs to be disseminated among the students. Ringxiety, as an indicator of the mobile phone addiction, was further supported by the fact that a similar proportion of students said they would be either very or extremely upset if there was network inaccessibility.

About, 86.8% of the respondents kept their cell phones off at night; and 13.2% didn't. This is a positive finding because problematic mobile phone use affects sleep quality as supported by White AG *et al*[17]. So the majority not

using phones at night may be a good sign that the majority may not experience insomnia due to mobile phones and may have quality sleep.

In 50% students committed that they could not stay without cell phones for a day, which implies that they are heavily relied upon mobiles and may be indicative of problematic cell phone use, similar to findings of Mitta A *et al*[18]. Subba SH *et al* also found that, nine out of 10 students would immediately replace a lost set[5].

Present article has elicited multiple facets of mobile phone usage like purpose of buying, commonly used tasks, presence of any hazards, and dependence with mobile phones. In addition, the study has also included smart phones – these are the strengths of the present communication. Only limitation is the study was conducted in a college, where 90% of the subjects belonged to higher socio-economic status. Main tasks done in mobile phone has been gradually changing over the time with introduction of the smart phones. Usage pattern is pretty different from the previous studies. Thus future research direction would be needed to find out the new underlying factors to address and limit the mobile phone usage pattern among students.

Conclusion

The pattern of mobile phone usage among the medical students appeared to be problematic, as a large proportion of students using it indiscriminately, spending much money, killing more time, suffering from various types of hazards and they use their phones at restricted times and places. Dependence on mobile phone and its hazards have become an issue nowadays due to the multiplicity of its functions. Rules and regulations need to be placed in time regarding its use is the need of the hour.

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Original Article

Maternal Death Reviews : an analysis in a teaching hospital in North Bihar

Tripti Sinha[1]

A maternal death review (MDR) is a medical audit which goes beyond merely enumerating the causes of maternal deaths. It investigates the community and hospital circumstances due to which currently available life-saving interventions could not save the woman's life. This is a retrospective analysis of facility-based MDR forms in a tertiary care teaching hospital in North Bihar. Seventy two deaths over a one-year period were analysed. Obstetric hemorrhage (antepartum and postpartum hemorrhage) and eclampsia were the leading causes of maternal deaths. Anemia was an important contributory cause. Twenty four cases were clearly documented as referred cases and were admitted in critical condition reflecting the community-based conditions contributing to delay 1 and delay 2 responsible for maternal deaths. Sub-standard care in the hospital after admission was also identified in some cases like poor management in postoperative period or in intensive care facilities of the hospital. Non-availability of blood was a serious limitation due to donor scarcity. Maternal deaths can be reduced only by combined socio-economic and medical interventions so that women in pregnancy and puerperium can receive timely evidence-based life-saving interventions.

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Key words **: Maternal deaths, maternal death reviews, medical audit, tertiary care hospital, obstetric hemorrhage, eclampsia, anemia, delay factors in maternal deaths, health care providers (HCPs).**

According to the International Statistical Classification of Diseases and related Health Problems-10 (ICD) a maternal death is defined as the death of a woman while pregnant or within 42 days of termination of pregnancy irrespective of the duration or site of pregnancy[1]. Global, national and regional analyses reveal that causes of maternal deaths remain the same although the contribution of each cause to the percentage of overall maternal mortality varies in different health-care settings. According to the Million Death Study collaborators' data of maternal mortality in 2014 in India, the causes in order of importance are haemorrhage 38%, miscellaneous causes 34%, sepsis 11%, abortion 8%, obstructed labor 5% and hypertensive diseases of pregnancy 5%[2]. The variations in the contribution to mortality figures, and the fact that while some women with the same pregnancy/puerperal complication or with co-morbid conditions in pregnancy survive while others succumb forms the basis of the rationale of maternal death reviews (MDR).

A maternal death review (MDR) is a medical audit-a qualitative in-depth analysis into the causes and circumstances surrounding maternal deaths at a health facility or even outside it. The difference between maternal mortality analysis and maternal death review is that while maternal death analyses is purely an academic exercise in delineating the disorder that lead to the death of mother, an MDR goes beyond the medical domain and looks into the reasons why the woman's life could not be salvaged despite effective treatment being available in current times[3]. As such it involves investigations into the conditions prevailing in the community as well as the health care facility where the woman died.

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Aims and Objectives

This study analyses the causes of maternal mortality in our hospital and the circumstances leading to failure to save the woman in our hospital. The objectives were

(1) To calculate the maternal mortality rate(MMR) in our hospital

(2) To estimate the proportion of maternal deaths in which delay 3 contributed solely or significantly to the death.

(3) To delineate the areas of substandard care in our hospital

(4) To formulate an action plan to remove such deficiencies in care within a feasible time-span.

Materials and Methods

This study is a facility-based observational study over a one-year period from August 2015-July 2016. It looks into deaths which occurred after admission of the pregnant, parturient or puerperal women at Sri Krishna Medical College Hospital, Muzaffarpur in North Bihar. A state-level orientation program was attended by one faculty member of the department. Other doctors working in the department were familiarised with the principles and practical aspects of MDR. A schedule for MDR sessions was set up in which each MDR form and case note was discussed at length. Each death was analysed to establish the underlying, immediate and contributory cause of death, the type of death (direct or indirect) and whether the death could have been averted at the facility.

The following data were compiled: maternal age, residential address (urban/rural), obstetrical history (GPAL), quality of antenatal care provided; period of gestation, diagnosis and general condition of the woman at the time of admission; whether she was a referred case, from where she was referred and the reason for referral; date and time of admission, onset of complication, delivery and death; details of delivery and outcome of pregnancy as relevant; interventions (D&E, CS, laparotomy, hysterectomy, instrumental delivery, manual removal of placenta, blood transfusion, type of anesthesia if required; admission to intensive care unit with details of care provided there; cause of death (primary/ contributory); whether death was antepartum, intrapartum or postpartum; whether autopsy was performed. A grid analysis of factors working in the family/personal life of the dead woman and logistical factors (infrastructure and manpower) in the health care system operating in each individual case was looked into (Table 1). The collected data was entered into MS Excel,analysed and the results expressed as percentage.

Table 1 — *Grid analysis chart of non-obstetrical/medical factors contributing to maternal deaths*

System	Example	Yes	No	Remarks
Personal/ family	Delay in woman seeking help			
	Refusal of treatment			
	Refusal of admission in previous facility			
Logistical problems	Lack of transport from home to health care facility			
	Lack of transport between health care facilities			
	Health service –Health service communication breakdown			
Facilities	Lack of facilities, equipment or consumables			
	Lack of blood			
	Lack of OT availability			
Health personnel problems	Lack of human resources			
	Lack of anesthetist			
	Lack of obstetrician			
	Lack of expertise, training or education			

Results

There were 72 maternal deaths between August 2015 and July 2016 at Sri Krishna Medical College Hospital, Muzaffarpur, Bihar. There were 8701 deliveries during that period was giving an appallingly high MMR of 827.

The socio-demographic data of the maternal deaths are shown in Table 2.

Table 2 — *Socio-demographic characteristics of maternal deaths (n=72)*

Characteristic	No of women (n) Percentage (%)
Residence :	
Rural	68 (94.44%)
Urban	4 (5.56%)
Religion :	
Hindu	58 (80.55%)
Muslim	14 (19.44%)
Distribution of maternal deaths according to period of year :	
August-October	13 (18.06%)
November-January	17 (23.61%)
February-April	12 (16.67%)
May-July	30 (41.67%)
Age :	
<20 years	2 (2.78%)
20-30 years	56 (77.78%)
>30 years	14 (19.44%)
Referred case :	
Yes	24 (33.33%)
Not documented/direct admission/unclear documentation	48 (66.68%)

Table 3 summarises the reproductive and obstetric status of the deceased women. The condition of the patient at the time of admission, the gestational period, onset of labor and postpartum/postoperative period at the time of admission and at the time of death and whether she needed and received blood transfusion are shown in Table 4.

More than 50% patients needing blood did not get it chiefly because attendants were not available or were not willing to give blood, and free blood could not be arranged by the hospital.

Fig 1 shows the primary underlying causes of the maternal deaths. The leading causes of death were obstetric haemorrhage (antepartum hemorrhage and postpartum haemorrhage-36.2%), antepartum and postpartum eclampsia (27%), postoperative complications (13.9%) severe anemia (8.33%)and miscellaneous

Table 3 — *Obstetric characteristics of the deceased women in the index pregnancy*

Characteristic	No of women (n) Percentage (%)
Gravidity/parity :	
Primigravida/para1	20 (27.78%)
Gravida 2/para 2-gravida 3-para3	27 (37.5%)
Gravida 4-para 5 or above	25 (34.72%)
Period of admission :	
Antepartum	39 (54.17%)
Intra-partum	20 (27.78%)
Postpartum	10 (13.89%)
Postprocedure (C.S./Pregnancy termination)	2 (2.78%)
Antenatal care :	
Yes	7 (9.72%)
No/undocumented clearly	65 (90.28%)

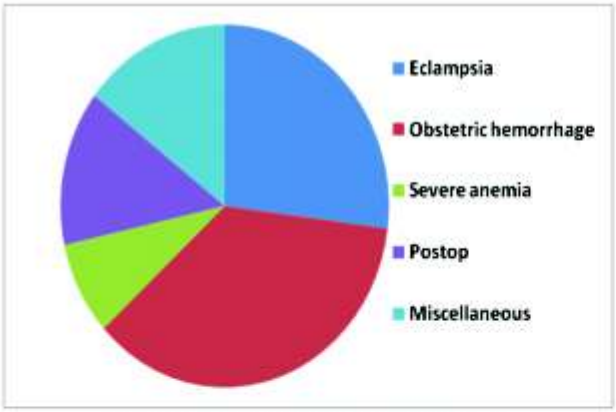

Fig 1 — Primary causes of maternal deaths

causes (about 14.57%). The miscellaneous group included hepatic encephalopathy 4%, heart disease 4%, sepsis 3%, respiratory problems 1%, cerebral malaria 1% and unclear causes 1%.

In 15 cases severe anemia was an important contributory cause for the maternal mortality.

Table 5 is a grid analysis of the 3 delay factors associated with the maternal deaths.

Discussion

In our study obstetric hemorrhage (APH, PPH) was the commonest cause of maternal deaths followed by antepartum and postpartum eclampsia. In other studies in different regions of India within the last decade the causes of maternal mortality are the same although the percentage contribution of each cause varies[3-8].

The maximum numbers of deaths were reported in mothers aged between 20-30 years. This is similar to the findings of Paul *et al*[3] in their study in another teaching hospital of Eastern India. It was, however, encouraging to note that there were no teenage maternal deaths in this series although elderly multigravida were in significant numbers (n=25, 34.72%).

MDRs are an important medical audit so that the resources of a hospital can be prioritised on the basis of the incidence of causes in the health care setup in which it is conducted. This is especially important in low-resource settings where cost-effectiveness of any intervention is very relevant. In our hospital the observation that many women died due to hemorrhage underpins the importance of providing efficient blood bank services and increasing public awareness regarding myths and misconceptions about blood donation.

Another important area to be looked into is the management protocol of the hospital. Labor ward inventory of injection Magnesium Sulphate and injection Labetalol as well as other items of the eclampsia tray need to be topped up on a regular basis by the staff in charge of the delivery suite. Eclampsia and PPH drills need to be repeated frequently so that labor ward staff remain conversant with their role while managing these complications.

Although non-medical factors (demand –side barriers)-delay 1: delay by patient and/ or family in seeking medical aid and delay 2 : delay in transport to and between health facilities-are often stressed upon as being responsible for most maternal deaths, it is equally important to accept the stark reality that many deaths occur after the woman has reached the health care facility where evidence-based life-saving interventions could or should have been available –delay 3 supply side barriers[9]. HCPs cannot intervene too effectively to eliminate delay 1 and 2. Facility-based MDRs provide insights into delay 3 in a particular health care centre so that remedial actions can be instituted eg, lack of essential drugs, trained personnel, blood transfusion facilities. WHO emphasises six essential building blocks for quality health care: services delivery, health workforce,

Table 4 — *Distribution of maternal deaths by delivery-associated characteristics*

Characteristic	No of women (n) Percentage (%)
Obstetric stage at admission period :	
Antepartum	39 (54.17%)
Intrapartum	20 (27.78%)
Postpartum	10 (13.89%)
Postprocedure	3 (4.17%)
General condition at admission :	
Stable	15 (20.83%)
Critical	
• altered sensorium	57 (79.17%)
• shock	
• cardiac failure	
• acute respiratory distress	
Admission-death interval :	
< 2 hours	18 (25%)
< 12 hours	49 (68.05%)
< 24 hours	56 (77.78%)
> 24 hours	16 (22.22%)
Obstetric stage at death :	
Antepartum	30 (41.67%)
Intrapartum	5 (6.94%)
Postpartum	23 (31.94%)
Postprocedure	14 (19.44%)
Blood transfusion :	
B.T. needed	35 (48.61%)
B.T. given	16 (22.22%)

Table 5 — *3 delays associated with the maternal deaths*

Type of delay	Specific detail of delay	No of csases
1	Delay in seeking aid	26
2	Transport delay	9
1+2	Delay in seeking aid+ transport delay	21
1+3	Delay in seeking aid + lack of blood	2
1+2+3	Lack of blood	1
3	Refusal of treatment at private hospital	1
	Lack of expertise/ training/education at hospital	1
	Lack of blood at hospital or non-availability of donor	1
	Lack of monitoring equipment/efficient ICU at hospital	1
Grid chart not filled up by primary informant		7

information, medicines, financing and governance[10,11].

Being an exercise in medical audit, MDRs generate some lessons to improve the quality of care being provided to women in pregnancy and thereafter. From this analysis of FBMDRs, the following disquieting observations and immediate remedial actions required were derived :

(1) Janani Suraksha Yojana has not improved antenatal care coverage although institutional delivery rate has increased dramatically. Hence anemia and eclampsiaare still rampant.

(2) Anemia eradication programs especially for women in reproductive age need to be implemented in the community on a war-footing.

(3) Pregnant women, their families and community health workers like ANMs and ASHAs need to be made aware of the warning signs of eclampsia and severe pregnancy-induced hypertension.

(4) Health-care providers in peripheral health care facilities need to be educated on early referral protocols before the condition becomes critical.

(5) IEC campaigns need to be strengthened in the community to dispel fears, myths and misconceptions regarding effects of blood donation on the donor if blood transfusion services are to be made efficient.

(6) Community-based MDRs (verbal autopsies) need to supplement FBMDRs so that delay 1 and 2 can be minimised.

(7) Care provided at the tertiary hospital itself did not measure up to the required standards. Care of the patients in obstetric wards before and after delivery and in the ICU needs to be improved.

(8) Case-note documentation was sub-standard in many cases.

(9) ASHAs who accompanied the patients to the hospital should be educated on the importance of regular ANC, BP check-ups and haemoglobin estimations.

(10) Postpartum contraceptive options are not routinely offered to women after delivery so that many leave the hospital with unmet need for contraception although several options free of cost are available in government hospitals. Lack of family planning (FP) counsellor and the extremely heavy case-load in obstetric units was chiefly responsible for the poor uptake of contraceptive methods.

Conclusion

Facility-based MDRs put each maternal death in the proper socio-economic-obstetrical context so that a holistic view of the case is taken and an overarching solution is sought in order to prevent such deaths in future. This study underscores the important point that although many patients reach the hospital in a critical condition due to delay 1 and 2 sdue to community-linked factors, as hospital-based HCPs clinicians and hospital administrators also need to address supply-side deficiencies (delay 3 factors) honestly and speedily rather than shift the blame solely towards the community conditions.

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Original Article

Analysis of factors influencing lack of response in patients under Revised National Tuberculosis Control Programme (RNTCP) protocol

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Tuberculosis (TB) is one of the most prevailing, contagious, chronic and a morbid infection. Our country has a high burden of TB. According to 2015 WHO statistics, India alone accounts to 23% of the total global incidence of TB cases. It is essential to provide complete and proper treatment as it is a contagious disease with high incidence. Though being curable, there is no 100% treatment success rate. If it is not treated properly, it can be fatal. To identify the various underlying factors affecting the treatment failure rate. Once the factors are identified, then the targeted strategies to address them can be formulated. It is a cross sectional study. Recorded cases of patients who were with sputum positive results despite undergoing TB treatment were included. The patients were interviewed using a questionnaire. Data were analysed using MS Excel. Among the retreatment cases most of them were from a low income profile. Most of them were malnourished. Nearly half of them had a positive history of TB in the surroundings. A quarter of them were co infected with HIV. More than half of them were smokers or alcoholic. There was discontinuity of drugs in half of the cases due to various side effects and some discontinued with a feeling of being cured. A few did not use the drugs regularly. Treating the underlying causes is essential to ensure successful treatment. Proper nutrition should be provided along with appropriate health education. There should be proper monitoring of the drug intake and any side effects should be treated immediately to ensure continuous usage.

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Key words **: Tuberculosis, RNTCP, DOTS, TB Retreatment, TB treatment failure reasons, factors affecting treatment.**

Tuberculosis is one of the most prevailing, contagious, chronic and a fatal infection. It is caused by the bacterial species Mycobacterium Tuberculosis.

India is the country with the highest burden of TB. The World Health Organization (WHO) statistics for 2015 gave an estimated incidence figure of 2.2 million cases of TB for India out of a global incidence of 9.6 million which nearly accounts to 23% and about 220,000 people die from the disease in India[1].

As it is a highly infectious disease, it can affect anyone but severity of the disease is more in those with any underlying comorbid conditions, especially in immuno-compromised states like HIV. At least one-third of people living with HIV worldwide in 2015, were infected with TB bacteria. People living with HIV are 20 to 30 times more likely to develop active TB disease than people without HIV. HIV and TB form a lethal combination, each speeding the other's progress.

Most people with TB are cured by a strictly followed, 6-month drug regimen that is provided to patients with support and supervision. Inappropriate or incorrect use of antimicrobial drugs, or use of ineffective formulations of drugs (such as use of single drugs, poor quality medicines or bad storage conditions), and premature treatment interruption can cause drug resistance which is much more difficult to be treated[2]. Multidrug resistant TB (MDR-TB) is a big problem because it is more difficult and costly to cure. MDR-TB must be treated with second-line drugs which are less effective, more expensive, and associated with more serious side effects than first-line treatments. MDR-TB takes at least three times longer to cure, usually 18-24 months and has a higher mortality rate overall than drug-susceptible TB[3].

The various suggested reasons behind failure of treatment may be inappropriate guidelines, poor quality, irregular supply, wrong delivery (dose/combination), drugs unsuitable due to drug resistance, lack of money for treatment and/or transport, actual or presumed side effects, lack of commitment to a long course of drugs[4]. Identifying the factors affecting TB treatment will give insights into the reasons behind lack of response and subsequently low treatment success rates.

Once the factors are identified, then the targeted strategies to address them can be formulated.

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Aims and Objectives

To identify the various underlying factors affecting the treatment failure rate of Tuberculosis under RNTCP protocol.

Proper identification and analysis of the factors will benefit the TB patients since the findings could be used to improve the quality of care resulting in the increased treatment success rates.

Material and Methods

It is a cross sectional study.

Recorded cases of patients in a DMC (Designated Microscopy Centre) of a Tuberculosis Unit (TU) in our district who were diagnosed with sputum positive results despite undergoing TB treatment were included in the study.

Sample size : A total of 46 cases were recorded for retreatment during the period of 1 year (September 2015 to September 2016) in the DMC.

Study Area : Designated Microscopy Centre – Dr.PSIMS and RF under the Tuberculosis unit – Gannavaram.

The DMC TB register was used to obtain the list and details of the patients. The register had records of the registered patient's name, contact number, address and date of starting treatment, HIV status, and classification of diagnosis.

It had a total of 198 TB patients notified during the period, September 2015 to September 2016 of which 46 were retreatment cases.

The patients were interviewed using a structured questionnaire. The data obtained were analyzed using MS Excel.

Observation and Results

The number of cases recorded for retreatment during the study period was 46, which constitutes nearly 23% of the total cases. Among the retreatment cases 91% were pulmonary cases and 9% were extra pulmonary. There was a male predominance of 81%. Most of them belonged to the age group of 21-40 years.

Among the cases 96% were found to be malnourished (It was detected using BMI as an index. Those with BMI value below 18.5 were considered to be malnourished). In this study the highest BMI value was 22.2 and the least was 15.2. Most of those who were malnourished (54%) had their BMI values between 17.0-18.4 (mild malnutrition).

BMI Values	Frequency
≥ 18.5	2
17.0-18.4	24
16.0 - 16.9	14
< 16	6

Among the cases 59% were from the low socioeconomic status (modified Kuppuswamy's socio-economic scale) and 57% of the subjects were educated (one who can read and write in any one language is considered educated). Twenty six percent of the cases were co infected with HIV and 11% of them were diagnosed with multi drug resistant TB. On considering diabetic status only 4% were found to be diabetic. Almost 87% of them had normal liver function tests and 54% of them had a positive history of Tuberculosis in the household or workplace. In the study 74% of cases were smokers and 61% were alcoholic. When discontinuity of drugs was considered, 55% of them did so because of actual or presumed side effects. Around 23% of them discontinued drugs with the sense of wellbeing and 22% of them did so as they were forgetful. There was no lack of supply of drugs in this study.

Factors	Frequency (Percentage)
Total TB Cases Recorded : 198	
Retreatment Cases (sample)	46 (23%)
1. Pulmonary	42 (91%)
2. Extra Pulmonary	4 (9%)
Malnourishment :	44 (96%)
Immunocompromised :	
1. Diabetics	2 (4%)
2. HIV Positive	12 (16%)
Resistance :	
Diagnosed With MDR TB	5 (11%)
Social Habits :	
Alcoholic	28 (61%)
Smokers	34 (74%)
History of TB in Surroundings :	
LFT :	25 (54%)
1. Normal	40 (87%)
2. Abnormal	6 (13%)
Discontinuity of Drugs (Reasons) :	
1. Sense of Well being	12 (23%)
2. Side effects	28 (55%)
3. Forgetfulness	11 (22%)
4. Lack of supply	0 (0%)

Discussion

Among all the TB cases (198) notified during a period of one year (September 2015-September 2016) 152 cases were newly diagnosed and 46 cases were previously treated cases. The retreatment cases in this study were nearly 23% of the total cases, which was nearly equal to a study done in Sikkim (27 %)[5].

This study was set out to identify the factors affecting response to TB treatment in a DMC in Gannavaram of Andhra Pradesh.

Among the retreatment cases, 91% were pulmonary and 9% were extra pulmonary. These values were similar to a study done in a tertiary center in Nigeria[6] (Pulmonary 88% and extrapulmonary 12%).

In this study 81% of the recorded cases were males while only 59% of them were males in the Nigerian study. 26% of them were found to be co infected with HIV while 20% were HIV positive in Nigerian study which had a sample size of 76. Among the HIV positive cases 75% of them were males in this study.

Eleven percent of the total cases were those with Multi Drug Resistant TB in this study. Here 45% of the cases of were in the age group of 21-40 years. There were two peaks in the age distribution of the patients, 21-30 years (30.8%) and >50 years (28.2%) in the Nigerian study.

When the factors affecting the TB treatment were

analysed, it was found that 96% of the recorded cases were found to be malnourished in this study. On comparison with a study done in Namibia[7], 69% of them did not have proper supply of food.

When the socio-economic status was taken into consideration, patients were scored using Kuppuswamy's Socio economic scale. In 59% of them belonged to a low income profile which was similar to a study carried out in South Africa. In a similar study in Indonesia 50% of them were with low income while the other 50% had a good income. The findings of this study are contraindicated with a study in India[8] which did not find employment status and income to be significant factors affecting the TB treatment.

Education regarding TB treatment is highly essential to complete the treatment successfully. When this factor is considered, 57% of them were educated. Only 9% of the recorded cases were illiterate in the Indonesian study. But a similar study done in Afghanistan cited that most of the cases recorded for treatment failure were illiterates which was not the case in this study.

Of all the total cases recorded, 4% of them were found to be diabetic. When the liver function tests were analyzed, 87% of the cases had normal LFT. As TB is a contagious disease, any history of TB in the household or locality or workplace was also considered. About 54% of them showed a positive history.

Around 74% of the recorded cases were smokers (daily and occasional). A daily smoker is someone who smokes any tobacco product at least once a day and an occasional smoker is someone who smokes, but not every day as per WHO. In a study in Morocco, smokers were twice as likely to fail tuberculosis treatment as non-smokers. Among patients with pulmonary tuberculosis in India, smokers were found to have a threefold greater risk of recurrent tuberculosis than non-smokers as per a study in South India[9]. But only 29% are smokers amongst those who failed the treatment in a similar study in Namibia. In 61% of the cases in this study were alcoholic (more than 80 gram alcohol in any form) whereas 57% drank alcohol in the Namibia study. Both the studies almost show a similar result regard to alcohol whereas they showed difference in smoking.

If the drugs were discontinued, various reasons for the discontinuity were analyzed in the study. There was discontinuity in 55% of the cases due any actual or presumed side effects like nausea, vomiting, headache, generalized weakness, arthralgia, skin rash. On comparison 47% of the patients also experienced similar side effects in the Namibia study.

In this study, 23% of the patients discontinued the drugs with a feeling of being cured. Almost same percentage of the patients, nearly 27% discontinued the drugs with a similar reason in a study in Namibia. Forty eight percent of them in Nepal[10] stopped the drugs as they were feeling better which is nearly double that of the result obtained in this study.

It was found that 23% of the patients in this study did not the use the drugs as they were forgetful. As per this study, there was no problem regarding the supply of drugs. They received all the drugs on time. There was a similar result regarding the supply of drugs in many other studies too.

Conclusion

On analyzing the results obtained in this study, malnourishment was found to be one of the major reason affecting TB treatment. Along with the regular supply of the drugs, proper nutrition should also be provided to ensure treatment success. Initiation of income-generating activities to improve food provision for patients on TB treatment is also essential.

Proper education to the patient and family members, regarding the treatment and its side effects is essential as the drug regimen is of longer duration. This could be done by giving proper guidelines and regular monitoring of the patients. Mass awareness programs should be initiated at the local level.

Smoking and alcohol can itself be a reason for poor nutrition and immune suppression. Hence to improve the quality of life, de addiction programs are to be initiated for those patients. Side effects due to drug regime have to be immediately attended and an alternative should be provided to ensure continuity of the treatment. There should also be regular supervision of the intake of drugs even by the family members to overcome the problem of forgetfulness. Complete usage of drugs is highly essential to prevent the emergence of more severe drug resistant forms.

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Original Article

Safety and performance of a levonorgestrel-releasing intrauterine contraceptive device : one-year outcomes of Fiona-1 clinical registry

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The objective of the Fiona-1 registry (CTRI/2016/03/006781) is to assess the safety and performance of levonorgestrel-releasing intrauterine device (LNG-IUD), Fiona. This was a prospective, open-label, single-arm study conducted at 19 centers in India. Healthy sexually active women (aged 19-40 years) having regular menstrual cycles had the insertion of Fiona LNG-IUD. All enrolled women were followed up at 1, 3, 6 and 12 months. The primary endpoint was failure of contraception defined as occurrence of intra-uterine or ectopic pregnancy in presence of study device or due to auto-expulsion of study device. Continuation rates, reasons leading to discontinuation, adverse events (AEs) and the pharmacokinetic profile (for a subset of 27 women) were evaluated. Amongst 309 parous women, implanted with LNG-IUD, clinical follow-up (FU) at 12-month was achieved in 294 women. During 12-month FU, no intra-uterine or ectopic pregnancy was observed. There wasn't any intra- or post-procedure perforation of uterus, endometrium or myometrium injury, pelvic inflammation or device expulsion (partial or full) reported till 12-month. The continuation rate of the LNG-IUD at 12-month is reported 95.47%. None of the women experienced any serious adverse event. However, 12 (3.9%) women discontinued the study due to AE. At 12-month FU, total 30 AEs were reported. The most commonly observed AEs were bleeding problems (11/30), abdominal pain (6/30), and spotting (5/30). Pharmacokinetic profile revealed levonorgestrel concentrations of 275.08±104.03 pg/mL and 227±84 pg/mL at 1 and 6 months, respectively. The results of this study demonstrated effective contraception and favorable safety profile of Fiona LNG-IUD over 12 months.

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The levonorgestrel-releasing intrauterine device (LNG-IUD) is one of the most effective methods of contraception; however, its uptake varies widely by country[1]. The use of LNG-IUD in a wide range of women,

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regardless of age and parity, requires minimal maintenance. Besides the contraceptive effect, LNG-IUD provides potential therapeutic benefits for a range of gynecological conditions including menorrhagia, symptomatic fibroids, endometriosis, and endometrial suppression with no systemic physiological effects[2].

Improvement in contraceptive services and uptake is crucial in India where a high unintended pregnancy incidence of 70 per 1000 had been reported. According to an estimate, in India, 13% of married women have an unmet need for contraception and 6% of married women use traditional methods of contraception with relatively high failure rates[3]. Globally 14.3% women in child-bearing age use intrauterine contraception. However, National Family Health Survey reported only 1.5% IUD user rate in India[4,5]. Nevertheless, the reported low IUD user rates explained by various reasons, such as poor accessibility, few competing brands and high cost, which underscore the need for safe, affordable LNG-IUD variants to meet women's contraceptive needs. Low utilization of LNG-IUD limits the evidence of its safety and performance in Indian women. Although several studies of LNG-IUD were conducted previously, their research focused on other indications of LNG-IUD, ie, menorrhagia, abnormal uterine bleeding, uterine leiomyoma[6-8].

The Fiona (Meril Endo-Surgery Pvt Ltd, Vapi, India) is a T-shaped, 52 mg LNG-IUD with a 20 µg/day release rate indicated for contraception up to 5 years. The main objective of the present study was to evaluate the safety and performance of a new contraceptive, Fiona LNG-IUD. The secondary objective was to perform a pharmacokinetic evaluation of plasma LNG concentration up to 5 years. This publication presents the 12-month interim results of the study.

Material and Method

Study design and population :

This open-label, prospective, single-arm, post-marketing study was conducted at 19 centers in five cities across India. This study protocol was reviewed and approved by Independent Ethics Committee and the study was conducted in accordance with the Declaration of Helsinki. The trial was registered at Clinical Trials Registry of India (CTRI/2016/03/006781).

The study enrolled 309 women between April 2016 and July 2017 who were willing to opt for long acting reversible contraceptives. The study included healthy females; aged between 19-40 year; having regular menstrual cycles (21-35 days); sexually active and in a mutually monogamous relationship for at least 6 months before enrolling in the study. Key exclusion criteria were: (1) a known or suspected pregnancy; (2) currently breastfeeding women; (3) history of trophoblastic disease, ectopic pregnancy or hydatidiform mole, pelvic inflammatory disease (PID), suspicion of malignancy of genital tract; (4) positive human immunodeficiency virus (HIV) test, Venereal Disease Research Laboratory (VDRL) test or gonorrhea; (5) congenital or acquired uterine abnormalities; (6) current genital infection, allergy to LNG or any component of intrauterine device.

Women who want long term contraception (and if required, her spouse) were counselled for the use of an IUD as their choice of contraception. Potential women were asked for their interest to participate in the study and written informed consent were obtained by the medically qualified person after explaining about the device, its use and alternative methods of contraception. Pre-enrolment assessment for her healthy being pertaining to general, systemic, menstrual and psychosexual health with her fitness to use contraception were conducted.

The device :

The Fiona is a T-shaped low-density polyethylene device with each vertical and horizontal arm of 32 mm (Fig 1a). The low-density polyethylene of T-frame is compounded with the radiopaque barium sulfate which makes it easily visible on X-ray. There is a brown monofilament polyethylene removal thread tied at the base of the vertical arm for identification and removal of the device. Iron oxide is used as a colorant in the polyethylene removal thread. The active ingredient, LNG, is dispersed in a silicone reservoir on the vertical stem of the device. This reservoir containing 52 mg of LNG is covered by a semi-opaque polydimethylsiloxane membrane which allows controlled release of LNG at the rate of 20 µg/day over a period of 5 years. The release of LNG gradually decreases after five years of use. Currently Fiona LNG-IUD is approved for sale in India.

Device insertion :

The device placement was performed by healthcare professionals using aseptic techniques according to instruction for use. A bimanual examination was performed before the insertion procedure. Vagina and cervix were cleansed with the suitable antiseptic solution. Gentle traction was applied after grasping the upper lip of cervix with a tenaculum forceps to align the cervical canal with uterine cavity. The uterine sound was performed to measure the depth and check the direction of the uterine cavity. In case of a retroverted uterus, traction was applied on the lower cervical lip. The uterine sound of 6 to 10 cm was considered safe for IUD insertion. Use of dilatation was advised if cervical stenosis was encountered. The insertion technique of LNG-IUD in uterine cavity is depicted in Fig 1b.

Pharmacokinetic analysis :

In a subset of 27 women, blood samples (each of 5 mL) were drawn at different time intervals through indwelling intravenous cannulation. The blood samples were taken at 1-, 6-, and 12-month intervals. Blood samples were

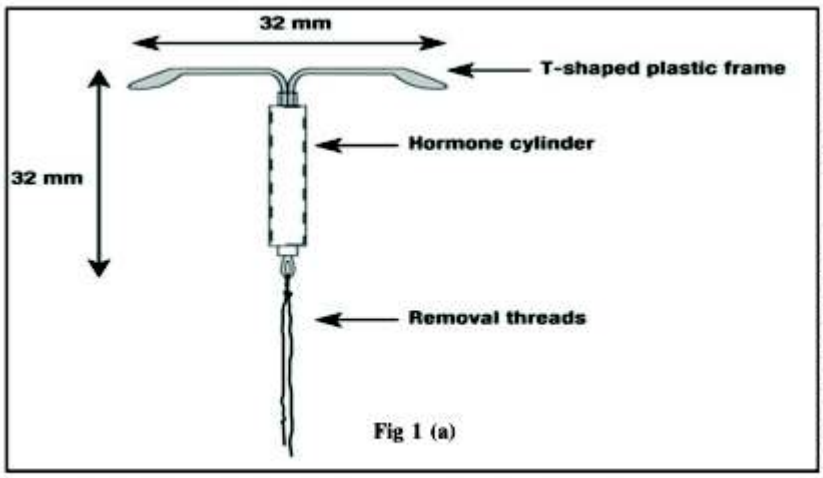

Fig 1 (a)

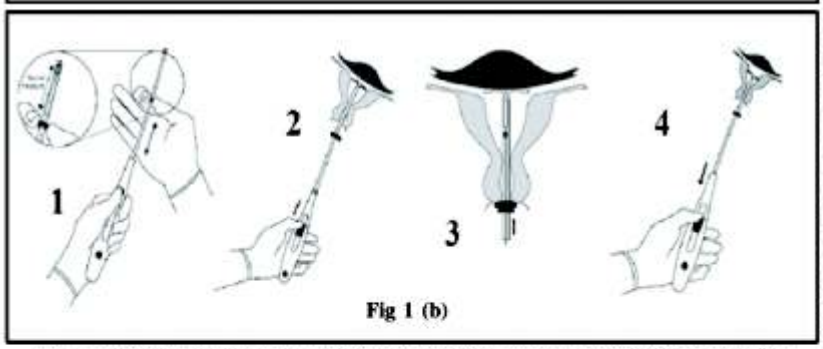

Fig 1 (b)

Fig 1 : (a) The levonorgestrel-releasing intrauterine system. (b) Simplified insertion procedure of the Fiona LNG-IUD; Step 1: After completion of sound measurement of uterine depth, adjust the depth by pushing the switch in forwarding direction. Step 2: The device is pushed into the uterine cavity and pulls the switch to open horizontal arms of Fiona. Step 3: Push inserted tube into the uterine cavity up to the fundus till flange touches to cervix. Step 4: To release Fiona, pull down switch and the thread is trimmed. Proper placement of Fiona in uterine cavity is assessed by ultrasound/X-ray examination.

anticoagulated with dipotassium ethylenediaminetetra acetic acid and centrifuged at 3000 ± 100 RCF for 5 minutes at room temperature to separate plasma. These separated plasma samples were stored at ≤20°C until analysis. The plasma samples were examined at Lambda Therapeutic Research Ltd, Ahmedabad, India. Plasma concentration of LNG was analyzed using liquid chromatography-tandem mass spectrometry method with the lower limit of quantification of 20.0 pg/mL and the upper limit of quantification of 15004.710 pg/mL. For calculation of pharmacokinetic parameters, the non-compartmental model was applied by using WinNonlin enterprise software version 5.3 (Pharsight Corporation, USA).

Study endpoints :

The primary endpoint was a failure of contraception defined as an occurrence of intra-uterine or ectopic pregnancy in the presence of study device or due to auto-expulsion of study device. Safety endpoints included; number of women with intra- and postprocedural perforation of uterus; number of women presented one or more conditions like significant endometrium injury, myometrium injury, PID, severe leucorrhoea or endometritis not relieved by medical intervention and required removal of device as well as expulsion or partial expulsion of the device.

At the baseline visit, demographics, vitals, physical examination, gynecological and medical history, hematology, previously used contraceptive method, urine pregnancy test (UTP), HIV, VDRL, and Papanicolaou test were performed. Scheduled clinical FUs were at 1 month (±10 days), 3 months (±15 days), 6 months (±30 days), and 12 months (±30 days) after LNG-IUD insertion and after that yearly (±30 days) for five years. AEs were recorded at each visit. The menstrual (inter-menstrual bleeding/spotting, dysmenorrhea, missed periods, vaginal discharge) and symptomatic (abdominal/back pain, headache, mood changes, acne or other skin/hair problems, breast tenderness, edema, weight gain) questionnaires were recorded at each FU.

Statistical analysis :

Descriptive statistics were performed for all variables; continuous variables were summarized by the mean ± standard deviation and categorical data was presented as frequency and percentage. Kaplan-Meier survival function was used to estimate the continuation rates for the LNG-IUD at 12 months after insertion. The analysis was performed using Statistical Package for Social Sciences, version 20 (Chicago, IL, USA). This was a non-comparative, prospective, post-marketing surveillance study. So there was no formal hypothesis testing and power calculation performed. We arbitrarily enrolled 309 women from theoretical predictions to draw the performance and safety pattern of the Fiona LNG-IUD.

Observations

Out of 318 women screened for the study, a total of 309 women (31.02 ± 4.90 years), were enrolled. Table 1 depicts baseline characteristics of the enrolled women. The device was successfully implanted in all women except one who suffered from a minor complication due to the tightness of cervical canal. Safety and clinical performance of an LNG-IUD in 306 women at 1-month, 301 women at 3-month, 295 women at 6-month and 294 women at 12-month FU are presented in this study. The detail of study disposition is represented in Fig 2.

Table 1 — *Demographics and baseline clinical characteristics of study population*

Demographics	Fiona LNG-IUD (N=309)
Age, years, mean ± SD	31.02 ± 4.90
19-30 years (%)	142 (45.9%)
31-40 years (%)	167 (54.0%)
Body mass index, kg/m², mean ± SD	24.1± 4.2
Marital Status, n (%) :	
Married	309 (100%)
Parity, n (%) :	
Parous	309 (100%)
One live birth	182 (58.90%)
Two	107 (34.63%)
Three or more live births	20 (6.47%)
Gynecological and obstetric history, days :	
Bleeding duration, mean ± SD	4.7± 0.9
Menstrual interval, mean ± SD	28.7± 2.7
Previous contraceptive use, n (%) :	
Barrier contraceptive	23 (7.4%)
Oral contraceptive	109 (35.3%)
Copper IUD	64 (20.7%)
Mechanical contraceptive	22 (7.1%)
None	91 (29.4%)

SD, standard deviation; IUD, intrauterine device

In the present study, no intra-uterine or ectopic pregnancy was reported till 12-month. None of the women reported intra-procedural or post-procedural uterus perforation, endometrium or myometrium injury, PID, severe leucorrhoea or endometritis and expulsion or partial expulsion. Besides these, there was no safety concern reported in 294 patients till 12-month.

The LNG release from Fiona is 20 µg/day directly get delivered into the uterine cavity. A mean plasma LNG concentrations of 275.08±104.03 pg/mL at 1-month (n=27) and 227±84 pg/mL at 6-month (n=23) have been reported in this study. The results of mean plasma LNG concentrations at the remaining FU will be reported in the upcoming report.

The continuation rate at 12-month for the Fiona LNG-IUD was 95.47 % is demonstrated by Kaplan-Meier curve (Fig 3). Fourteen women (4.53%) were reported to have discontinued use of Fiona LNG-IUD at 12-month; among which 13 had discontinued before 6-month of study duration. Out of 14, 12 (3.9%) women discontinued the study due to AE, and other two women (0.65%) had withdrawn consent due to personal reasons. There were multiple reasons reported for the discontinuation, as listed in Table 2. Bleeding-related reasons (n=6) and abdominal pain (n=4) were mentioned more frequently by women who were discontinuing the study. One woman requested removal of LNG-IUD due to constant spotting for 25 days after device implantation; whereas one woman felt discomfort with device and weight gain after implantation which resulted in LNG-IUD removal.

None of the women reported serious adverse event associated with Fiona LNG-IUD in the present study. However, a total of 30 AEs occurred in 21 women till 12-month FU. These AE included bleeding problems (11/30), abdominal pain (6/30), spotting (5/30), pelvic pain (2/30), weight gain (2/30), body pain (1/30), lower abdominal discomfort (1/30), nausea (1/30) and discomfort due study device (1/30). The cumulative AEs at each FU till 12 months are summarized in Table 3.

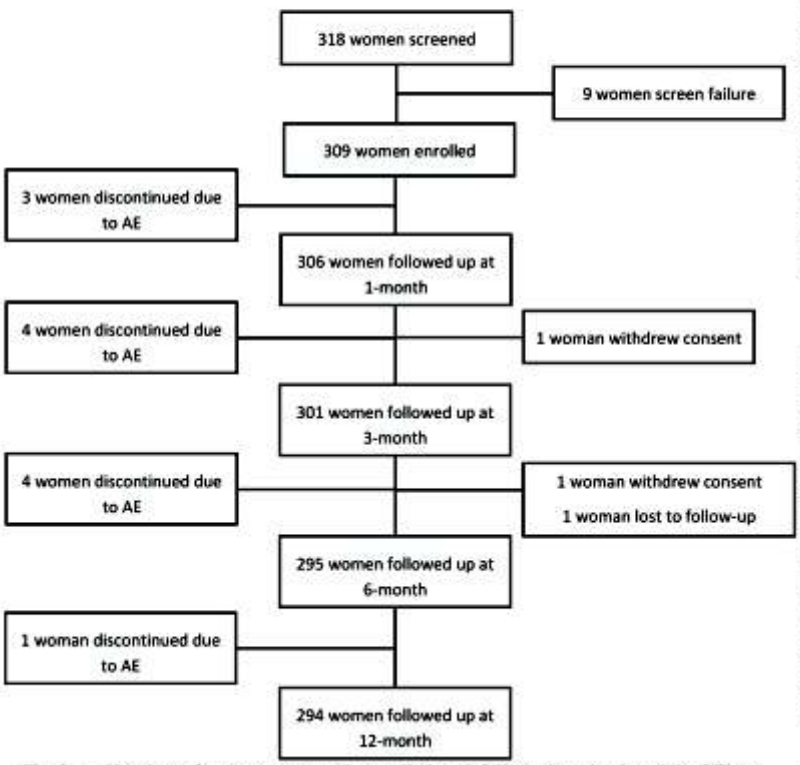

Fig 2 — Number of women screened, enrolled and followed up in the trial of Fiona LNG-IUD; AE : Adverse event

Discussion

The study was planned to demonstrate the performance and safety of Fiona LNG-IUD for contraceptive use. The contraceptive performance of the device up to 12-month was established based on contraception failure which was not reported in the 294 studied women. Although 30 AEs were documented till 12-month FU; however, none of the enrolled women experienced uterine perforation, endometrium or myometrium injury, expulsions or any other complication up to 12-month FU.

Contraception is the primary indication of Fiona LNG-IUD. The insertion technique

Table 2 — *Listing of women who discontinued treatment with LNG-IUD during the study*

Age (years)	Time of discontinuation (months)	Reasons for removal
39	0.2	Bleeding
36	0.2	On-and-off lower abdominal pain, relieved by medications
35	0.9	Spotting
28	1.7	Bleeding
31	1.7	Bleeding
29	2	Constant bleeding after device insertion
39	2.5	Constant bleeding after device insertion
36	2.5	Subject Withdraw Consent due to personal reason
31	4.7	Bleeding
30	4.7	Lower abdominal pain, not resolved by medications
32	5.6	weight gain, uncomfortable with device
36	5.7	Lower Abdominal Pain not relieved by medications
31	5.9	Subject Withdraw Consent due to personal reason
33	11.4	Moderate abdominal pain, not resolved by medications

of Fiona is simple and can be easily performed by health care professional with least training required. The presence of descending transverse arms serves to protect against unintentional perforation of the uterus during insertion. The primary mechanism of action of LNG-IUD targets the endometrium by releasing LNG into the uterine cavity. The high local LNG concentration thickens cervical mucus, makes the endometrium thin and decidualized, and also produces an unsuitable environment for sperm survival and fertilization, which represents a key mechanism of contraceptive action of LNG-IUD[9].

The performance of Fiona LNG-IUD was determined by the failure of contraception (occurrence of intra-uterine or ectopic pregnancy) in the present study. In 1-year FU survey, the pregnancy rate was significantly lower for 52-mg LNG-IUD compared to different copper-IUDs10. Previously reported ectopic pregnancy rates for LNG-IUD users ranged from 0.02% to 0.2% at 12-month[10]. However, several studies have reported no pregnancy during use of the LNG-IUD for over a period of 5 years[11-13]. Likewise, our study does not report any ectopic or intra-uterine pregnancy which depicts good performance of LNG-IUD till 12-month.

Low uterine perforation rate at the time of insertion (1.4/1000 insertions) was reported in EURAS IUD study[14]. ACCESS IUS study at 3-year FU reported 0.17% uterine perforation rate as well as 3.5% expulsion rate; most expulsions (80.6%) occurred in the first year of product use[15]. However, there wasn't any perforation of the uterus or expulsion of study device reported in the present study at 12-month, which demonstrates good safety profile of the study device. Several previous studies reported PID incidence ranging from 0.1% to 1.9% in the months following insertion[16,17]. In the present study, there was no incidence of pelvic infection following insertion.

One-year continuation rates for standard intrauterine device (IUD) initiation in previously published studies ranged from 80% to 88% for 52 mg LNG-IUD[18,19]. It was observed that most of the women discontinued the use of IUD as a consequence of bleeding and pain[19-21]. The similar results were observed in the present study as 6 out of 12 women reported bleeding problems and 4 out of 12 women complained abdominal pain as a reason for their discontinuation. Frequency and irregularity of bleeding are common changes in the majority of women during the first few months after insertion of the LNG-IUD[20,22]. However, the pattern of both bleeding and spotting decrease considerably after prolonged use of LNG-IUD in above-mentioned studies. In the present study, most AEs were reported at 3- and 6-month after LNG-IUD implantation and the occurrence of AE considerably decreased at 12-month FU.

Nevertheless, LNG-IUDs are meant to act locally at the uterine cavity; low level of LNG is absorbed into systemic circulation swiftly. It was observed that maximum plasma LNG level reached after few hours of insertion and the plateau of 150-200 pg/mL after the few weeks of insertion

Table 3 — *Cumulative adverse events*

Type of adverse event	In hospital (N=309)	1-month FU (N=306)	3-month FU (N=301)	6-month FU (N=295)	12-month FU (N=294)
Bleeding problems	0	5	10	11	11
Pelvic pain	0	0	1	2	2
Spotting	0	2	3	5	5
Abdominal pain	0	2	2	5	6
Ache/Body pain	0	1	1	1	1
Lower abdominal discomfort	0	0	1	1	1
Nausea	0	0	1	1	1
Weight gain	0	0	1	2	2
Uncomfortable with study device	0	0	0	1	1
Cumulative events, n (%)	0	10	20	29	30

FU: Follow-up

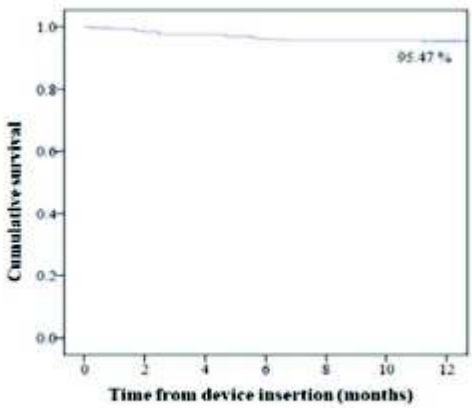

Fig 3 — Kaplan–Meier survival curve of IUD continuation

was reported for Mirena LNG-IUD[23]. LNG concentrations after short-term use of Fiona at 1-month (275.08±104.03 pg/mL) and 6-month (227±84 pg/mL) appeared parallel (p=0.11) to the 6-month (n=36) LNG concentration 195±68 pg/mL of an LNG-IUD LILETTA[24]. This shows an admissible pharmacokinetic profile of the study device.

Large sample size would have provided more insights into the usage of LNG-IUD and its safety and performance in Indian women, especially in relation to events such as expulsions of device and safety. Notwithstanding these limitations, the study will provide factual findings of pharmacokinetic profile, safety, and performance of LNG-IUD at 5 years, which could be constructive for future investigations in Indian women.

In conclusion, Fiona LNG-IUD showed favorable safety profile and good performance in most of the Indian women who remained in the study at 12-month. The claim of long-term contraception of Fiona LNG-IUD is to be assessed from future results of 5-year FU.

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Conflict of interest :

Dr Ashok Thakkar and Bhavi Patel are full-time employee of Meril Life Sciences Pvt Ltd, India. The other authors declare no conflicts of interest.

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Case Report

Orbital varix — a case report

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To present a rare case of unilateral orbital varix. A 65-year-old woman with unilateral orbital mass was examined with color Doppler ultrasonography (USG), computed tomography (CT). The presenting symptom of the patient was proptosis in right eye at will, at any time, just by stooping down for a few minutes. There was no associated ocular motility disorder or diplopia Ocular examination was normal with the exception of an 18 millimetre proptosis of right eyes during Valsalva manoeuvre. The comparison of contrast-enhanced spiral CT scan obtained before and after Valsalva manoeuvre revealed the diagnosis of orbital varix. Color Doppler US revealed a large venous connection between the lesions and systemic circulation. Clinical presentation of orbital varix is unusual. Different radiological tools help for the confirmation of the diagnosis and delineate the anatomic and the dynamic features of the lesion.

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Key words **: Enophthalmos, Hertel exophthalmometer, Orbital varix, Proptosis, Phleboliths.**

Orbital varices are low- flow venous malformation occurring due to vascular dysgenesis. It typically presents as enophthalmos at rest in the patient when the lesions are not engorged. A progressive intermittent proptosis on valsalva manoeuvre or on bending diagnostically implicates for orbital varix[1]. The diagnosis is established via contrast-enhanced spiral CT during a Valsalva manoeuvre (or other means of decreasing venous return) which reveals characteristic enlargement of those engorged veins. Phleboliths may be present on imaging which are often diagnostic. Treatment is usually conservative. Surgery is reserved for relief of significant pain or for cases in which the venous malformation causes vision-threatening compressive optic neuropathy.

Case Report

A 65 year old female from Amtali, Agartala attended eye OPD at Agartala Govt Medical College & G B Pant Hospital on 05-08-2013, with a complaint of forward protrusion of the right eyeball on stooping down, for the last 20 years. The bulging was painless in nature. It was of gradual onset. Initially she felt some vague discomfort over right eye followed by fullness over right eye. The patient was able to produce proptosis of the right at will, at any time, just by stooping down for a few minutes. On bending forward, coughing, sneezing, squatting it increases in size. The patient reported the same on sleeping in right lateral position. There was no associated ocular motility disorder or diplopia but disappears on standing. There is associated feeling of foreign body sensation in the same eye There was no history of any trauma or of varicosities anywhere else in the body. The past history and the family history were without any significance.

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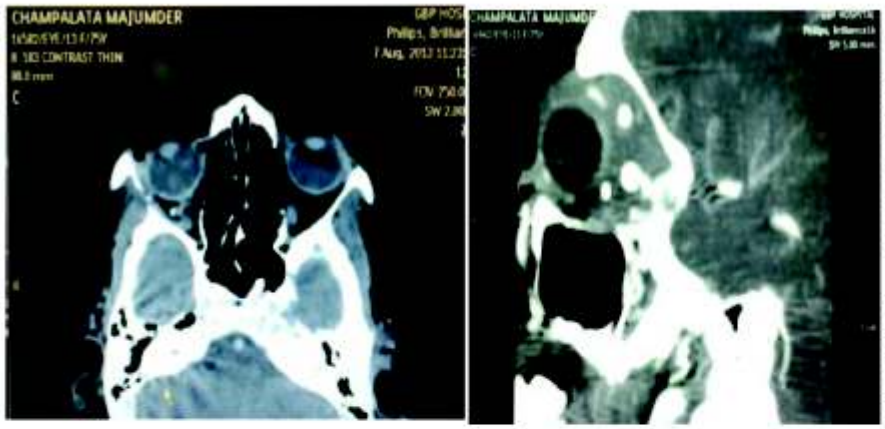
Examinations — On Ocular examination her vision was 3/60 right eye and 6/24 left eye. The right eye showed a distinct enophthalmos with slight widening of the palpebral aperture as compared with the left eye. The superior palpebral furrow was very deep. Anterior segment of both eyes were normal except nuclear sclerosis grade 3 both eyes. Both pupils had a normal light reaction. Eye motility was normal in all gazes (Fig 1).

Fig 1 — Proptosis increases with valsalva manoeuvre

In primary position there was proptosis in right eye. The proptosis was axial. Increases with valsalva manoeuvre. Forward protrusion of the eyeball started within a few seconds of stooping down and reached its maximum in about 1.5 minutes. It disappears on compressing the eye ball with eyelid closed. As the patient assumed the erect posture the proptosis disappeared, the right eye assuming its previous enophthalmic position. There was no pulsation or thrill palpable, after the production of proptosis. Auscultation of periorbital area was negative. Measured by hertel exophthalmometer, 18 mm of proptosis was elicited by valsalva manoeuvre.

B-mode ultrasonography (US) showed both masses enlarging with Valsalva manoeuvre. Colour Doppler US demonstrated ante grade venous flow within the lesions and retrograde venous flow during the Valsalva manoeuvre.

On contrast-enhanced spiral CT scan, well-circumscribed



Figs 2&3 — CT scan showing well-circumscribed homogeneous lobulated soft tissue mass with multiple calcified densities (Phlebolith)

homogeneous lobulated soft tissue mass with multiple calcified densities mainly in the superomedial orbital region extending to the orbital apex were noted, enlarging markedly with Valsalva manoeuvre with forward displacement of the eyes. The right orbit showed expansion. Phleboliths were visualised (Figs 2&3).

CT angiography was done and was confirmed.

Conservative management has been advocated. The patient has only been asked to refrain from trauma and certain body postures which might induce Intraorbital venous pressure increase.

Discussion

Primary orbital varix which is a congenital venous malformation usually presents with painless intermittent proptosis. Orbital varix usually originates from the superior ophthalmic vein, probably due to a congenital weakness of the vascular wall. Induction of venous stasis either by bending the head forward, or coughing, forced expiration or pressure on the jugular veins, leads to pronounced and rapid protrusion of one eye[2].

Orbital varix may be associated with venous malformations elsewhere in the body. Vascular abnormalities may be present in the conjunctiva or eyelids and localised venous dilatations on the forehead and scalp are also reported. In our case there was no other vascular abnormality elsewhere in the body.

The typical clinical picture of orbital varices is unilateral intermittent proptosis. Here in our case our patient complained so mainly on bending the head forward, coughing, etc. she complained of periocular fullness and pressure appearing with bending forward which was same as that of Bulent Yazici et al case report[2].

Recurrent attacks leads to pressure atrophy of the orbital tissues and retro bulbar fat resulting enophthalmos on erect posture as seen in our case[3]. The narrowing of the palpebral aperture during proptosis is due to suffusion of the conjunctiva and eyelids due to venous stasis. The view expressed by Walsh (1957) that it can be attributed to an involuntary effort to favourably influence the amount of proptosis does not seem to be a probable explanation of the narrowing of the palpebral aperture in our case[4].

A contrast-enhanced spiral CT scan of the orbits is a very useful diagnostic aid as this can delineates other orbital and adnexal pathology such as orbital fat atrophy, orbital varices, and orbital changes associated with pathology in the maxillary sinus. In presence of a Phlebolith within the vascular channels in CT scan, the diagnosis of varices can be confirmed[5]. Biopsy should be avoided because of the risk of haemorrhage.

On Clinical grounds alone, difference between tumours and true vascular abnormalities may land up in diagnostic dilemma. Orbital venography is essential as a preoperative diagnostic tool. Its CT Image finding that add up to the typical clinical picture for making the diagnosis of orbital varix highly conclusive[6].

Treatment of varices mainly dictates surgery. The various surgical modalities of orbital varix includes Injection of sclerosing agents into the orbit, Aspiration of the retro bulbar space, Ligation of the superior ophthalmic vein, Artificially-induced electrical current and total removal of the lesion[7]. Surgical excision is technically difficult and often incomplete because the lesions are friable and bleed easily. Surgical recommendation is reserved for recurrent thrombosis, pain, severe proptosis and optic nerve compression[8]. But in our case Conservative management has been advocated. The patient has only been asked to refrain from trauma and certain body postures which might induce Intraorbital venous pressure increase.

Conclusion

A case of intermittent proptosis at will by stooping down and its complete resolution on assuming the erect posture without any pulsation or thrill, there being no history of trauma is presented. The cause is evidently an orbital varix.

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Case Report

A rare case of multiple cardiac rhabdomyomas

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Rhabdomyoma is the commonest benign cardiac tumor of childhood, although it rarely will be found in early adulthood. They originate within the myocardium, typically in the ventricles, and may be multiple in up to 90% of cases. Up to 50% of these hamartomas are associated with index cases of tuberous sclerosis. The majority of patients are asymptomatic, and most of these rhabdomyomas will spontaneously regress. However, some may produce life-threatening cardiac failure due to left ventricular outflow tract obstruction or arrhythmias, and these will require surgical resection.

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Key words **: Rhabdomyoma, cardiac tumor.**

Rhabdomyoma is the commonest benign cardiac tumor of childhood originating within the ventricular myocardium and may be multiple in up to 90% of cases. Up to 50% of these hamartomas are associated with index cases of tuberous sclerosis. The majority of patients are asymptomatic and most of these will spontaneously regress. However, some may produce cardiac failure due to left ventricular outflow tract obstruction or arrhythmias and require surgical resection. We present a case of multiple rhabdomyomas in a 20 days old male child, 2D echo suggested multiple solid hyperechoic varying size masses in bilateral ventricular free wall and interventricular septum. One of them was seen obstructing right ventricular outflow tract. All these findings were confirmed on cardiac CT.

Case Report

A 20 days old male child presented with complains of dyspnoea, cyanosis and feeding difficulty. So he was investigated and 2D echo was done to rule out underlying cardiac abnormality. 2D echo suggested multiple solid hyperechoic varying size masses in bilateral ventricular free wall and interventricular septum. One of the lesions was seen obstructing right ventricular outflow tract.

Patient had no history of seizures or any skin lesions. Family history was insignificant. Ultrasound of cranium and abdomen was unremarkable.

CT cardiac was also performed to rule out any other associated cardiac abnormality. CT was performed after injecting non-ionic contrast through antecubital vein. These images were reviewed with MIP (maximum intensity projection), SSD (shaded surface display) and Volume Rendering. CT Findings were multiple varying size non-enhancing filling defects that appeared isodense to myocardium involving bilateral ventricular free wall and interventricular septum. One of the lesions was projecting in right ventricular outflow tract. Hypoplastic confluent pulmonary arteries were seen.

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Discussion

A cardiac rhabdomyoma is type of benign myocardial tumor. Cardiac rhabdomyomas are often multiple and can represent up to 90 % of cardiac tumors in the pediatric population[1]. The majority are diagnosed before the age of 1 year. The estimated incidence is at ~ 1 in 20,000 births[4]. They may arise anywhere in the myocardium but are commoner in the ventricles (may involve the left ventricle more)[5].

Clinical presentation :

The majority of cardiac rhabdomyomas are asymptomatic although there can be wide clinical spectrum. On occasion they may present with ventricular outflow tract obstruction or refractory arrhythmias. There is a well known association with tuberous sclerosis, with over 50% of all cardiac rhabdomyomas found in patients with later confirmed tuberous sclerosis[2,3]. The remainder of these tumors occurs sporadically or in association with congenital heart disease. Although most infants with tuberous sclerosis have cardiac rhabdomyomas, the prevalence of these lesions in this population decreases with increasing age, because of spontaneous tumor regression and better survival of patients without cardiac tumors[1]. Other complications include valvular compromise or disruption of intra-cardiac blood flow leading to congestive heart failure and hydrops.

Pathology :

It is a hamartomatous lesion consisting of cardiac muscle tissue (derived from embryonal myoblasts). They grossly appear as yellow-tan solid, circumscribed, unencapsulated lesions. Microscopically, a characteristic spider cell is seen which a large clear cell is with cytoplasmic strands composed of glycogen extending to the plasma membrane[8].

Radiographic features :

Ultrasound / Echocardiography **—** May be seen as one or more solid hyper echoic masses located in relation to the myocardium. Small lesions can mimic diffuse myocardial thickening (Fig 1).

***CT* —** Seen as filling defects iso to hypodense compared to myocardium involving ventricular wall or interventricular septum (Fig 2).

***MRI* —** T1 : relatively well defined masses iso intense to adjacent myocardium

T2 : relatively well defined masses hyper intense to adjacent myocardium

Computed Tomography (CT) and Magnetic Resonance (MR) can provide very useful additional information for a better characterization of the tumor[6,7]. CT does not only facilitate the study of the heart but it also allows for the study of the adjacent mediastinum and extra cardiac anomalies. However CT does not provide real time images like the echocardiography and it is not useful for the analysis of valvular mobility. MR is better than CT for the characterization of soft tissues and is very useful for the evaluation of intramural masses. Rhabdomyomas detected with US may be missed with CT or MR imaging and vice versa. Thus, these procedures may be complementary. In general, US better demonstrates small (<0.5 cm) or entirely intramural lesions.

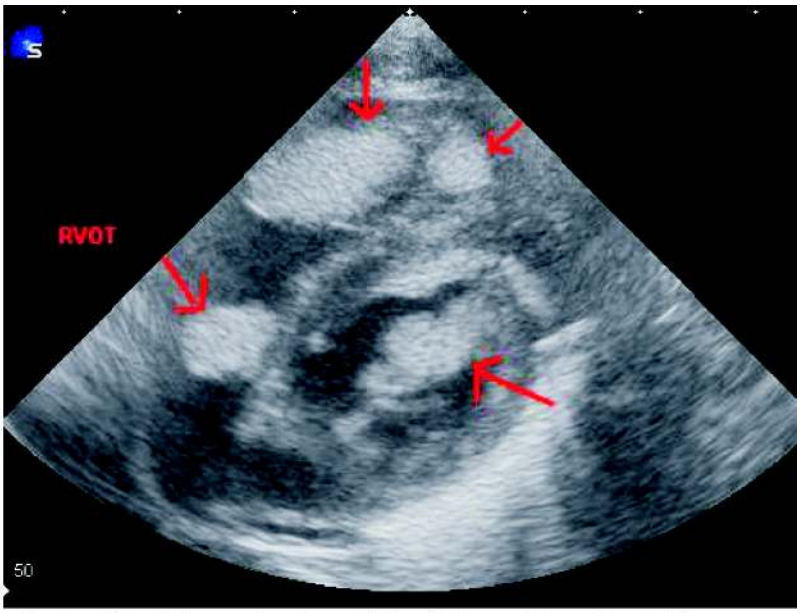

Fig 1 — 2D echo image showing multiple solid hyperechoic cardiac rhabdomyomas involving the ventricular septum and ventricular wall (arrows). One of the lesions is projecting in right ventricular outflow tract

Treatment and prognosis :

In most cases no treatment is required and these lesions regress spontaneously. Patients with ventricular outflow tract obstruction or refractory arrhythmias respond well to surgical excision. The overall prognosis is dependent on the number, size and location of the lesions as well as the presence or absence of associated anomalies.

Our patient was put on regular monthly follow-up to monitor any complications.

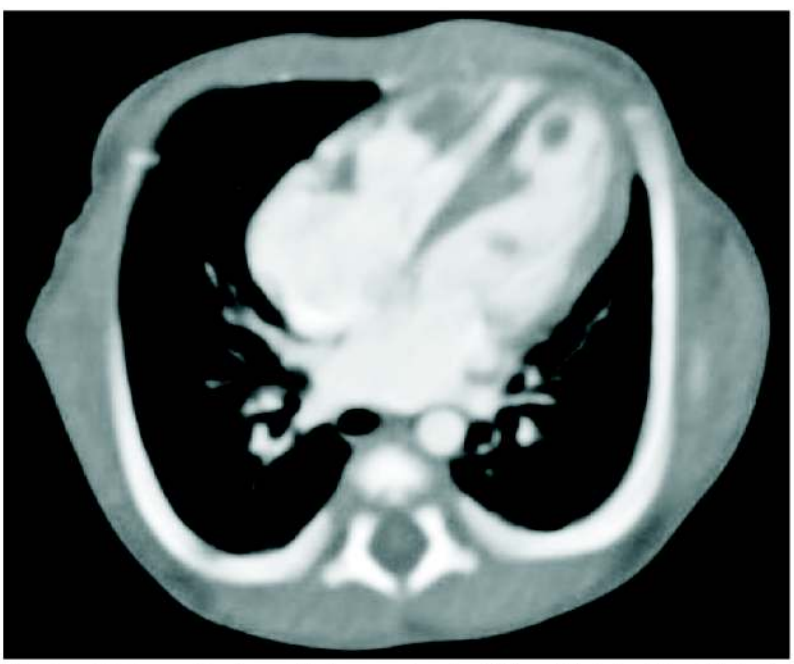

Fig 2 — CT image showing multiple non-enhancing filling defects involving bilateral ventricular free wall and interventricular septum

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Case Report

Giant common bile duct stone

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A forty year old female presented with pain in epigastrum, right hypochondrium and jaundice for the last one month. On examination the patient had mild pallor and icterus. Ultrasound of abdomen showed multiple stones in the gall bladder and a large stone in the common bile duct with dilated intrahepatic biliary radicals. She was posted for cholecystectomy and common bile duct exploration when a large stone of size approximately 8 X 5 cm was found to be impacted in the common bile duct along with multiple small stones. Cholecystectomy and common bile duct exploration was done.

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Key words **: Common bile duct stone.**

Choledocholithiasis is presence of gall stones in the common bile duct. Primary choledocholithiasis, formation of stone in the CBD is rare, occurs with bile duct stasis. Patients with CBD stones present with pain abdomen, jaundice, dark coloured urine, clay coloured stools, fever and chills (cholangitis), gall stone pancreatitis. Diagnosis is made by history, physical examination, blood tests, imaging (ultrasound, MRCP). Treatment consists of cholecystectomy with removal of CBD stone, ERCP with sphincterotomy.

Case Report

A forty year old hindu female from Palamu (Jharkhand) presented in the outpatient department on 16/06/2012 with pain right upper abdomen for the last one month. She was also having yellowish discoloration of eyes and urine for last one month. She had similar pain three years back.

Examinations — On examination there was mild pallor and icterus. Her abdomen was soft with no organomegaly or any palpable lump. All routine investigations were done. Haematological examination showed Hb(10),Total Count (8300), P(64%), L(32%), E(02%), M(02%), B(0%), slightly increased bilirubin (1.4), increased alkaline phosphatase(504), SGOT and SGPT were within normal limits. Routine examination of urine and chest X-ray were normal. Abdominal ultrasound showed stone in gall bladder and common bile duct with IHBR dilatation.

After preparation she was posted for surgery on 27/06/2012. Abdomen was opened by right paramedian incision, gall bladder was found to be contracted and fibrosed, filled with multiple stones. Common bile duct was dilated. It was opened and a large stone of size 8X5 cm was taken out along with multiple small stones (Fig 1).

Cholecystectomy was done by fundus first method. Common bile duct was washed with normal saline. Postoperative period was uneventful.

Discussion

In most of the cases of choledocholithiasis solitary stone is found in the common bile duct. Walter and Snell reported solitary stone in $^{2}/_{3}$ of their cases[1]. Mayo Robson and Dobson counted 88[2] and Judd and Marshal[3,4] more than 100. In most case a stone lies in the lower part of common bile duct. Giant gall bladder stone have been reported; one measuring 4 inches[5] in circumference and another $6^{1}/_{2}$ inches long and 6 inches thick[6] have been reported. Bahuleyan reported a giant common bile duct stone measuring 6.5 X 3 cm[7].

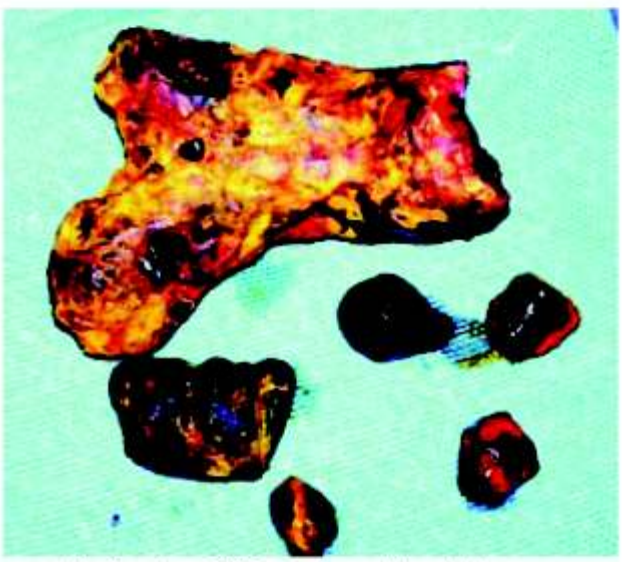

Fig 1 — Large CBD stone along with multiple stones

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Letter to the Editor

[The Editor is not responsible for the views expressed by the correspondents]

James Parkinson : The Forgotten Hero

Sir, — Involuntary tremulous motion, with lessened muscular power, in parts not in action and even when supported; with a propensity to bend the trunk forwards, and to pass from a walking to a running pace: the senses and intellects being uninjured .....

Year 2017 marks the 200th anniversary of James Parkinson's description of the disease that bears his name and that affects an estimated 5 million people worldwide. Working as a medical surgeon in London, James Parkinson was the first to connect the dots when confronted with a handful of patients with similar involuntary tremors and symptoms of muscle weakness. In 1817, he published his findings in his seminal 'Essay on shaking palsy', a 66 page essay on six cases, the three of his own patients and the three who he saw in the street.

He referred to the disease that would later bear his name as paralysis agitans, or shaking palsy. He distinguished between resting tremors and the tremors with motion. It was almost 50 years after Parkinson's death before the significance of his Essay was fully appreciated and the shaking palsy renamed 'Parkinson's disease' in his memory. It was Jean-Martin Charcoat who coined the term "Parkinson's disease" some 60 years later. Parkinson erroneously predicted that the tremors in these patients were due to lesions in the cervical spinal cord.

James Parkinson (11 April 1755 - 21 December 1824) was an English surgeon, apothecary, geologist, palaeontologist, and political activist. He is most famous for his 1817 work, An Essay on the Shaking Palsy in which he was the first to describe "paralysis agitans". The symptoms identified by Parkinson two centuries ago are still used to diagnose the disease today. Although unable to identify a cause for the condition, Parkinson's remarkably accurate description of the symptoms, and the disease in all its different stages, eventually led to it being named in his honour.

The Enlightened Mr. Parkinson by Dr. Cherry Lewis, Honorary Research Fellow at the University of Bristol, tells the story of Parkinson's life as an apothecary surgeon (similar to today's GP) in Hoxton, then a village on the outskirts of London. It was a time when epidemics festered in the dirty and overcrowded tenements, infant mortality was fifty percent, and no anesthetics were available for those unfortunate enough to require surgery. Smallpox killed ten per cent of the population, so when Edward Jenner discovered a vaccine, Parkinson worked with him to establish vaccination stations across London.

In 1812 Parkinson assisted his son with the first described case of appendicitis in English, and the first instance in which perforation was shown to be the cause of death.

Parkinson's interest gradually turned from medicine to nature, specifically the relatively new field of geology, and palaeontology. He began collecting specimens and drawings of fossils in the latter part of the eighteenth century. He took his children and friends on excursions to collect and observe fossil plants and animals. His attempts to learn more about fossil identification and interpretation were frustrated by a lack of available literature in English, and so he took the decision to improve matters by writing his own introduction to the study of fossils.

He revealed an unknown world, populated with 'hyenas the size of bears' and 'enormous marine animals', all of which both enthralled and terrified his readers. His exquisitely illustrated Organic Remains of a Former World placed the study of fossils on the scientific map of Britain before the subject even had a name.

When awarded The Royal College of Surgeons' first Gold Medal, it was not for his medical publications that Parkinson was honoured, nor even his Essay on the Shaking Palsy, but for his ground-breaking work on fossils.

Parkinson became a political activist after the French Revolution, which many in Britain supported. He wrote numerous outspoken publications which harangued a corrupt and incompetent Government using the pseudonym 'Old Hubert', for many were imprisoned and even transported to Australia for such seditious activities. When caught up in an alleged plot to kill 'mad' King George III, Parkinson put his own life on the line trying to save his friends.

Parkinson also contributed several papers to William Nicholson's "A Journal of Natural Philosophy, Chemistry and the Arts", and in the first, second, and fifth volumes of the "Geological Society's Transactions". He wrote a single volume 'Outlines of Orytology' in 1822, a more popularise work.

Parkinson belonged to a school of thought, Catastrophism, that concerned itself with the belief that the Earth's geology and biosphere were shaped by recent large-scale cataclysms. He cited the Noachian deluge of Genesis as an example, and he firmly believed that creation and extinction were processes guided by the hand of God. His view on Creation was that each 'day' was actually a much longer period, that lasted perhaps tens of thousands of years in length.

We have come a long way since the publication of 'Essay on shaking palsy', but we haven't found what James Parkinson was looking for: a way to stop the disease in its tracks. We'll continue working until we do.

April 11th, James Parkinson's birthday, is World Parkinson's Day. Each year in April, thousands of people across the globe roll up their sleeves to raise awareness for the disease and the consequences for all those affected by it. To commemorate this year's bicentennial edition, the Flemish Parkinson League has organised thought-provoking event on April 23, 2017 in Ghent, where patients, clinicians, family members and researchers got together, to look back, but more importantly, to look forward to new treatment approaches on the horizon, as a salute to this forgotten man.

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Nation wide Protest by IMA against draconian NMC Bill

Hunger Strike by IMA MSN

Ujjain Branch, MP


Chandigarh Branch


GMC, Ernakulam


IMA MSN Gaya


Kollam Branch


GGH, Eluru


Kanyakumari Medical College Students

Gadag Branch


Ambikapur Branch

Madurai Branch, TN


Villupuram Branch, TN


Rajbhawan March, ThiruvananthaPuram


Guntur Branch

UP State

Ottapalam, Kerala

Andhra Pradesh State Branch


Ranchi Branch, Jharkhand

Massive Protest against NMC Bill in Delhi

Leaders from all over the Country assembled,marched and got arrested






National President of Indian Medical Association, Dr Santanu Sen speaks on National Medical Commission Bill 2019 on the floor of Rajyasabha on 1st August, 2019 in the capacity of Hon'ble Member of Parliament, Rajyasabha

Thank you very much, respected Deputy Chairman Sir, for giving me this scope in the post-lunch session. Though I strongly believe that this Bill is for the medical fraternity, the doctors' community and for medical education, the entire medical fraternity, doctors' community and medical students are on the road since the last two weeks against this draconian National Medical Commission Bill. So I strongly believe that this Bill should not have been discussed today.

Even then, I am forced to give my maiden speech as it is being discussed now. Sir as it is, this is my maiden speech. I could have been very happy and very pleasant but to be very honest, I am standing here with a heavy heart, with profound grief and sorrow because the entire medical profession is against this Bill. Sometimes the House seems to be like a house of prudence but sometimes it seems to be a house in a hurry to trample upon a well-set tradition of Indian Parliament.

Before I come to my main speech, I would like to clarify certain points which have been mentioned by the Treasury Bench. I believe before a Bill gets discussed, the leaders and the Ministers of the Treasury Bench who want to speak on that Bill should be briefed properly because the Honourable leader Bhupendra ji said that this is the same Bill has already been sent to a Select Committee. It is for the information of this august House that this is absolutely incorrect. The National Medical Commission Bill, 2017 was introduced on December 29, 2017 and the same Bill was sent to the Standing Committee on January 2, 2018 at 2:15pm. The Standing Committee made some recommendations. Then as the 16th Lok Sabha got dissolved, that Bill lapsed.

This 2019 Bill is an absolutely new Bill. The previous Bill had 59 clauses, this 2019 Bill contains 61 clauses. There is a clause 32 regarding which nothing was mentioned in the previous Bill. So I think before speaking on something, we should be briefed properly.

Sir I must endorse the learned professional colleague of mine, the respected Minister Sir. He has said that this is probably the biggest reform. Yes of course, it is the biggest reform if a Bill like this allows total corporatisation of medical education. If this is not the biggest reform then what is? Sir, I endorse this sentence here, it says it will be written in golden letters. Of course it will be written in golden letters because this Bill is going to be a mother of quackery in Indian Parliament and in Indian history. If it is not written in golden letters, what else will be written in golden letters?

I would like to clarify one point. We all know that there was a charge against the Medical Council officials but at the same time we must keep it in mind that after proper investigation, finally the CBI had to give those people clean chits. This is for the information of all of you.

Our respected Minister stated that out of 25 members of National Medical Commission, 21 are doctors. Yes I do admit 21 are doctors but all of them are Central Government employees. Can you expect a Central Government employee to say something against the desire of the Government of India?

Let me come to my point. First of all, we all know that if parents bring something for their children and the children refuse to accept it because they think it will not be good for them, then the parents, thinking of their children's impending future, will take that thing away from the children. But here, our parents, the Government is bringing something for the medical fraternity, the children, and the children are refusing it because of impending danger, but our present Government is mercilessly bulldozing them to force them to accept this National Medical Commission Bill. This is absolutely unfortunate.

But then what else we can expect from our Government when our Honourable Prime Minister in 2018, sitting at Westminster Hall, London, had portrayed the doctors' community of his own country as a bribe-taker in front of the British Parliament and media.

Ten thousand doctors were there on the roads of Delhi on the 29th of this month Three hundred doctors including myself were arrested by police on the 29th of this month. Lots and lots of doctors across the country are on strike against his Bill. But can we expect our respected Minister, a doctor himself, to consider the protestors' views? It's rather that we can expect him to be guided by his party's diktat, a party that has already created a record in this Parliament by bringing so many Ordinances, by bypassing scrutiny of so many Bills in this session, by extending the parliamentary session like anything. So we are used to it, Sir, there is nothing new about the attitude of this Government.

Let me clear my views, not only as a Member of this august House but as the national president of the Indian Medical Association. Again this had to be expected of me because yesterday one of the learned Members of Parliament from their party spoke on camera, saying that Dr Santanu Sen is giving an anti-national statement. I am fighting for the fraternity. Is anyone who opposes them anti-national?

I categorise the Bill as anti-federal because firstly, the Bill completely outrages federalism as explained in the Constitution of India. In Section 4 of this Bill there is the chairperson, there are 10 ex-officio members, 14 part-time members, totalling 25. Among those 14 part-time members, three are on non-rotational basis and 11 on rotational basis. In the rotational category, six part-time members would be from among the members of States and Union Territories, who are members of the Medical Advisory Council, and five would be from among the nominees of the State and Union Territories who are nominated from among the elected State Council members.

And the terms of the rotational part-time members are for two years and of the non-rotational members, four years. As such, if

one State gets represented this year, it will remain unrepresented for the next 12 years in the case of State nominees, and for 14 years in the case of State Council nominees. There could not have been a worst marginalisation of the State. On the contrary, as per the existing system, every year every State gets three representations in the existing systems.

Sir, moreover, in Sections 45(1) and 45(2), it is written that the ultimate power lies with the Government of India and each and every State is bound to abide by the directives given by the Government of India. This National Medical Commission Bill snatches autonomy of the State Medical Council as those will remain bound to follow the decision of the National Medical Commission. Sir, how this Bill centralises power is that, not only are all the members of the National Medical Commission handpicked from among the Government of India's servants, as I said earlier, but also, in order to accommodate retired bureaucrats, the age limit for superannuation has been extended by up to seven years. The members of the National Medical Commission will be a set of puppets whose strings will be in the hands of the Government, and who will dance to its tunes.

The Government of India has deputed a secretary-general on the Medical Council of India's board of governors. The recently-proposed National Medical Commission Bill is totally silent on the post of the secretary-general on the board of governors.

Sir, let me come to the point of capitation fee. I would like to inform that till date, as per the Supreme Court guidelines, admission fees of 85 per cent seats of the private medical colleges are regulated by the Government. As per Clause 10(i) of this Bill, not only will 50 per cent of the seats be sold freely but for the remaining 50 per cent too, this board will not prescribe the capitation fee. So indirectly, hundred percent seats of all private medical colleges will be open for sale. Can you believe after this that rural meritorious students from remote districts of the country will be able to even dream of becoming a doctor? This National Medical Commission Bill will indirectly lead to the mushrooming of private medical colleges and nothing else.

As my learned speaker said before me, there is a provision of third-party inspection. Now what is that? We are saying that the MCI was corrupt. We are trying to shut the door of corruption and you, on the other hand, are opening the floodgates of corruption. This is very unfortunate.

Moreover this Bill says that inspection of new medical colleges should be discretionary. What do you mean by 'discretionary'? If today I open a medical college, it is absolutely discretionary whether my medical college will be inspected or not. Therefore I can collect crores and crores of rupees as capitation fee but my medical college will not be inspected by for three to four years. After three years, by which time I might have accumulated crores and crores of rupees, I can shut the college down and go away. And then what will happen to the students? What will be the fate of the students? It is not clear in this Billr.

As per Section 15, I have the following questions before my respected Minister, regarding the exit examination. I would like to know whether the final year MBBS examination and the exit examination will be the same, or not. If all other MBBS exams are conducted by Health University, and that particular examination is being conducted by the National Medical Commission, then who will confer the degree? Because as per the University Grants Commission Act and the University Act, only the Health University can confer only degrees. So when the entire examination system is been conducted by a particular State university, who will confer the degree?

Now to the aspect of MCQs. As you know, in our medical profession, usually there is classroom teaching for only one year, after which we go to clinics, we get to visit patients, and these are the most crucial types of training for becoming a doctor. In the final year MBBS, in the practical examination, we answer questions on medicine, surgery, gynaecology, etc. But if this next exam is completely an MCQ test, then you can run a distance course as well – open a medical college, no hospital needed, and run a distance course. Students will just sit in their homes and study and then answer MCQs in the name of examination. But then, if I become a doctor this way, will you allow me to examine you as a patient? Because the clinics can be avoided if this Bill gets passed. On the contrary, if our learned Minister says that they will be conducting a centralised practical exam for 70,000 students, it will not be possible.

Another question, if a student passes an exam this year, he gets licence to practice but if his score is less, he doesn't get admission in PG. He starts practicing as a doctor and at the same time he studies hard; he appears in the same exam after one year, but unfortunately he fails. So will I remain a doctor, will my licence will be cancelled? It is not clear from the Bill, Sir.

In the current system, if a student fails, after six months he gets a chance to appear in a supplementary exam. Nothing is explained in this Bill. For how many times will a doctor or a student be allowed to appear in this exit exam? How to get admission to AIIMS? Will it be as per the same next exam? It is to be clarified by our learned Minister.

Sir, don't you think that this Bill is going to benefit the foreign-educated graduates? Don't you think that graduates of our own country should be given some benefit rather than those getting their MBBS from China, Pakistan, Bangladesh, Russia, etc.? By keeping both the degrees at a par, you are actually indirectly giving more advantage to those who are getting their MBBS degrees from outside, which is very unfortunate.

What will happen to the service quota? Won't the doctors who go to render their service in villages get the advantage of service quota? If the service quota is abolished, doctors will hardly go to villages to render services.

As per Clause 32, they are making medicine into a master of quackery course by allowing lab technicians, ECG technicians, X-ray technicians, compounders, ambulance drivers, who are directly or indirectly associated with the medical system, to get a license. Sir, we fought against this clause tooth and nail. At least there is a provision that Ayush doctors will be trained but in this case, anyone can become a doctor, anyone can be allowed to prescribe like a doctor.

Our respected Minister has said that he has accepted 49 recommendations out of the 56. It is something like accepting the plate and throwing away the food. I can show you the ATR report which is with me. They have accepted certain points only.

And last but not the least, I will let you know that there are so many fallacies in this Bill that it should be sent to a Select Committee. Otherwise I'll say this Bill is going to be of the ambiguous, for the ambiguous, by the ambiguous. Please send it to a Select Committee. Otherwise, kahin aisa na ho, yahan se jane ke baad koi mujhe poochhe, haal kya hai tumhara karobar ka, aur humko yeh na bolna pare ki, hal, mat poochho mere karabar ka, main aaina bech raha tha andhe ke sheher mein.

NATCON 2019

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80th ANNUAL MEETING OF CENTRAL COUNCIL OF IMA
(Organised by Bengal State Branch, IMA)
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