DMC/DC/F.14/Comp.2971/2/2024/ 19th September, 2024

**O R D E R**

The Disciplinary Committee of the Delhi Medical Council examined a complaint of Shri Harish Chander Batra, r/o A-2, Ground Floor, South Extension Part-1, New Delhi-110049 (referred hereinafter as the complainant), alleging medical negligence on the part of the doctors of Moolchand Khairati Ram Hospital, New Delhi, Lala Lajpat Rai Marg, Near Moolchand Metro Station, Block M, Lajpat Nagar III, Lajpat Nagar, New Delhi- 110024, in the treatment of the complainant’s wife Smt. Shashi Batra(referred hereinafter as the patient), resulting in her death on 24.11.2016.

The Disciplinary Committee perused the complaint, written statement of Dr. Madhu Handa, Medical Administrator, Moolchand Hospital, enclosing therewith written statement of Dr. Anil Malik and Dr. Shashirekha, copy of medical records of Moolchand and other documents on record.

The following were heard in person :-

1) Shri Harish Chander Batra Complainant

2) Dr. Anil Malik Consultant Surgery, Moolchand Khairati Ram Hospital

3) Dr. Shashirekha Consultant Pathology, Moolchand Khairati Ram Hospital

4) Dr. Ishita Jha Medical Superintendent, Moolchand Khairati Ram Hospital

It is noted that as per the complaint, Shri Harish Chander Batra has alleged that wife (the patient) Smt. Shashi Batra had fibroids in her uterus, which has been detected and were present for some period of time. On visits to local diagnostic clinicians, the clinicians and the doctors informed the patient that presence of fibroids within the uterus was common occurrence and she needs not to concern herself with the presence of fibroids. However, it would be pertinent to state that the said clinicians and the doctors had additionally cautioned her that in the event of fibroids causing her any pain or discomfort; the same would require to be attended and clinically managed at that stage which was not the case with the patient. Sometimes in October, 2015, the patient started experiencing various symptoms such as menstrual bleeding, pain in lower abdomen, nausea and vomiting, amongst other incidental issues. In view of the relentless pain, which was being caused to his wife, he initially took the patient for an ultrasound examination with a local diagnostic centre, which confirmed the presence of large uterine fibroids and gall-stones (referred to as calculi), in the report. The consultants at the diagnostic lab advised the patient that this growth was causing pain and recommended the patient to undergo immediate surgery for removal of uterine fibroids. In view of the suggestions made, he took the patient alongwith ultrasound report for a consultation with Dr. Anil Malik, who was the Senior Surgeon at MoolchandKhairati Ram Hospital. Upon examination of the reports, Dr. Anil Malik recommended that the patient get admitted for immediate surgery, i.e. hysterectomy. Prior to the surgeries, several pre-surgical tests were conducted which did not reveal any other related issues. During the hysterectomy, Dr. Anil Malik sought his (the complainant) permission to removal gall-stones through a follow-up surgery i.e. cholecystectomy, which permission was granted by him (the complainant). Consequently, on 25th October, 2015, two surgeries were performed on the patient. The extracted mass which included the uterus, cervix, bilateral tubes and the ovaries with degenerating fibroids were sent for the biopsy. The biopsy was conducted by Dr. Shashi Rekha, who was the pathologist attached with MoolchandKhairati Ram Hospital. The pathology report wrongly indicated that there were benign cells in the extracted mass and; hence, wrongly concluded that there were no further issues with the patient. Basis this finding, as recorded in the pathologist’s report, Dr. Anil Malik recommended that there were no further issues which would threaten the patient’s health and consequently, gave her a clean bill of the health and recommended for her immediate discharge. The biopsy which finds mention above is foundation of the entire case against MoolchandKhairati Ram Hospital, since this biopsy completely failed to detect presence of any cancerous cell. It is further brought to the attention that reports prepared by Dr. Shashi Rekha, was reviewed by Dr. Anil Malik, who apart from being the operating surgeon, and was also a senior team leader. Dr. Anil Malik after looking at the reports repeatedly reassured him as well the patient that the reports did not indicate any problems and; hence, strongly recommended the patient for discharge. The fact that Dr. Anil Malik chose to rely simplicity on the biopsy report which incorrectly failed to detect the presence of the cancerous cells, without corroborating the same with additional evidence clearly reveals that Dr. Anil Malik was patently negligent. It was in these circumstances that the patient was recommended for discharge on 29th October, 2015. Dr. Anil Malik repeatedly assured him (the complainant) that the patient had no recurring symptoms and no further course of treatment was advised. Moreover, no formal report was prepared by Dr. Anil Malilk, who simply directed MoolchandKhairati Ram Hospital to prepare a standard Discharge Summary showing a clean bill of health to the patient. Moreover, Dr. Anil Malik strongly advised him (the complainant) that he need not concern himself with any further course of treatment for the patient. In Discharge Summary, Dr. Anil Malik recommended medications for period of five days post-discharge. Given that the patient underwent the procedures of removal of hysterectomy and gall-stones in close proximity to each other, he (the complainant) repeatedly enquired whether any follow-up consultancy was required. However, on every such occasion, Dr. Anil Malik repeatedly assured him (the complainant) that no such follow-up consultancy was required and he did not need to worry about it anymore. Sometimes in May, 2016, patient started experiencing continous coughing, symptoms, which persisted for more than one month. Due to the seriousness of the symptoms, he took the patient for an x-ray examination on 06th June, 2016 to a private clinic which conducted chest x-ray. In the chest x-ray, the private clinic pointed out that there were multiple cannon-balls like shadows which indicated towards growth of cancerous cells. Immediately, he took the x-ray report to Dr. Anil Malik, who upon aperusal of the same, categorically opined that the cannon-ball like shadows indicated towards the growth of the cancerous cells within the chest/lungs and, moreover, stated that it seemed that the same was metastasized. Dr. Anil Malik furthermore expressed shock on seeing the x-ray report and indicated that there was nothing that he himself could do. He (Dr. Anil Malik), therefore, suggested that the patient be taken for a full body PET-CT scan to determine the extent, to which, the cancer had spread. He (the complainant) decided to get the PET-CT done from a local diagnostic centre, i.e. House of Diagnostics. He approached the House of Diagnostics on 06th June, 2016 i.e. immediately after the meeting with Dr. Anil Malik. However, since he approached in the evening hours, the PET-CT scan was only carried out the next day i.e. 07th June, 2016. The report of PET-CT scan was provided by the House of Diagnostics on 08th June, 2016 wherein they not only confirmed the cancer, but revealed that the cancer had spread from the uterus, and reached the spine, lungs and other major organs/tissues. The report of House of Diagnostics categorically states that there was leiomysarcoma of uterine origin. Moreover, the report also revealed that a mass abutting from the vaginal vault was observed in PET-CT scan. Given the confirmation and determination of extent of cancer, his (the complainant) younger son Shri Akshit Batra addressed an email dated 08th June, 2016 to Dr. Lalit Kumar, Head, Department of Medical Oncology, Dr. B.R. Ambedkar Institute Rotary Cancer Hospital, AIIMS, seeking his opinion in this respect. Dr. Lalit Kumar vide his response email dated 09th June, 2016 suggested review of the original biopsy slides prepared by Dr. Shashi Rekha of MoolchandKhairati Ram Hospital. Furthermore, Dr. Lalit Kumar recommended for review of cell-block/cell-slides. It was when Dr. Lalit Kumar suggested for review of cell-blocks that he (the complainant) first got inkling that something was not correct and that the major issue was concealed by Dr. Shashi Rekha as well Dr. Anil Malik. Basis the opinion and recommendation of Dr. Lalit Kumar, he (the complainant) approached IRCH, AIIMS, who upon a detailed study of the PET-CT report and film, conclusively held that the patient had stage-IV cancer. However, AIIMS as a means of elimination, still required, him (the complainant) to obtain the cell-slides/blocks prepared by Dr. Shashi Rekha for another opinion. It is in these circumstances that his son (Shri Abhay Batra) approached MoolchandKhairati Ram Hospital and required them to hand over of cell-slides/tissue blocks prepared by Dr. Shashi Batra. While his son was waiting to submit the slides, he was informed that AIIMS as a policy did not return the cells-slides after the examination. He (the complainant), thereafter, approached Rajiv Gandhi Cancer Institute and Research Centre who after initial examination of the PET-CT film and report, recommended for fresh biopsy and immunehistochemistry (IHC). Accordingly, the fresh biopsy and IHC examination was conducted on 17th June, 2018 which confirmed cancer. Further, Rajiv Gandhi Cancer Institute and Research Centre also recommended, in addition to AIIMS, for review of cell-blocks/slides to identify the primary origin cancer. The Medical Oncologist at Rajiv Gandhi Cancer Institute and Research Centre suggested chemotherapy sessions for the patient to try to contain the cancer, as curing the cancer at that stage was not possible. Due to logistical considerations, he (the complainant) approached Max Hospital, Saket, as it was closer to his home than Rajiv Gandhi Cancer Institute and Research Centre. Max Hospital in its preliminary review, called for biopsy report of Rajiv Gandhi Cancer Institute and Research Centre and on examination of the biopsy report of Rajiv Gandhi Cancer Institute and Research Centre, Max Hospital confirmed the fact that the patient was suffering from leiomyosarcoma, and it was at a very advanced stage. Max Hospital further suggested that the patient undergo chemotherapy sessions to alleviate the suffering. He wishes to point out that Max Hospital called for cell-blocks/slides prepared by Dr. Shashi Rekha for the review. On review of the cell-blocks/slides, prepared by Dr. Shashi Rekha, Max Hospital confirmed the fact that the said slides were compatible with grade-II cancer, which had, at some point post-surgery in October, 2015, metastasized to various parts of the body, including the backbone, lungs and liver and moved to an advance stage in seven months post-surgery, as was evident from the PET-CT scan report dated 08th June, 2016, which clearly indicates that the cancer was already at stage-IV in June, 2016 and beyond cure, leading to the unavoidable conclusion that the doctors at MoolchandKhairati Ram Hospital were medically negligent in conducing the biopsy test and providing the patient required medical treatment at the very outset. The confirmation by Max Hospital about the failure to diagnose and detect cancer cells in the initial biopsy by Dr. Shashi Rekha, was the clear indication that the doctors and pathologist at MoolchandKhairati Ram Hospital were medically negligent in conducting the initial biopsy. The patient underwent six chemotherapy sessions from June, 2016 till November, 2016 at Max Hospital. Given that Max Hospital confirmed the cancer, he (the complainant) approached Tatal Memorial Hospital for another opinion in July, 2016, which conclusively confirmed leiomyosarcoma of uterine origin. Moreover, it was found that the cancer was aggressively spreading. As such, Tata Memorial Hospital also suggested for review of original cell-slides/cell-blocks. Due to worsening condition of the patient, she was again admitted to Max Hospital, Saket, for period of eleven days, where, she was being managed in the ICU care facility. The patient developed breathing difficulty and was consequently on breathing support, as her lungs were badly affected. On 22nd November, 2016, Max Hospital exhausted all possible solutions and; hence, recommended the patient to take LAMA (Leave Against Medical Advice). Consequently, the patient was discharged LAMA on 23rd November, 2016. Therefore, his (the complainant) case in brief is that the failure to detect cancer in October, 2015, led to delay in the treatment, which consequently resulted in delay in the medical strategy by nearly seven months, which caused the unchecked spread of the cancer to the backbone, live and the lungs, and which ultimately, on 24th November, 2016, resulted in the death of the patient. Therefore, in light of the above state factual matrix, it is amply clear that Dr. Anil Malik and Dr. Shashi Rekha grossly erred in not detecting the cancer at an earlier stage, despite the fact that the extracted mass biopsies revealed that there was suspicious cancerous growth. Therefore, in light of the aforementioned facts and circumstances which unequivocally point that the concerned doctors, medical staff, attendants, path-lab assistants and pathologist are collectively grossly negligent and unethical in the treatment of the patient as such, it imperative that the Delhi Medical Council urgently and immediately takes step to suspend the medical licenses of all concerned personnel, as detailed above, for sake of public health at large.

On enquiry by the Disciplinary Committee the complainant stated that he was not provided the slides by MoolchandKairati Ram Hospitalbut only the blocks, for purposes of review excised specimens, for histopathological examination at other hospitals.

Dr. Anil Malik, Consultant Surgery, MoolchandKhairati Ram Hospital stated that he conducted laparoscopic cholecystectomy on this patient (Smt. Shashi Batra), which was uncomplicated. He saw the biopsy report of uterus removal by Dr. Sadhana Kala/Dr. Yuvakshi Juneja and it was benign. It was seen by the gynaecologist team also, who did the abdominal hysterectomy. The allegation of any kind of negligence against him is totally wrong, as he followed the protocol.

Dr. Shashirekha, Consultant Pathology, MoolchandKhairati Ram Hospital stated that the allegation she failed to correctly diagnose and detect the caner, i.e. leiomyosarcoma as part of her duty to carry out microscopic examination of the tissue samples made available for the biopsy, is absolutely without any basis. In the complaint, it is alleged that the cell blocks/slides prepared by MoolchandKhairati Ram Hospital, on a review by Max Hospital, Saket states that the patient had leimyosarcoma of uterine origin and that the said slides were compatible grade-II cancer. The allegation is without any basis and must fail for the reason that the complainant has made deliberately false averments to the following effect in relation to the review undertaken at the Max Hospital, as evident from the document produce :-

1. The specimen reviewed at Max Hospital, were cell blocks and not the same slides on which the microscopy was done at MoolchandKhairati Ram Hospital.
2. Repot from Max Hospital states that they received all the ten blocks of TAH and BSO alongwith the gall-bladder.
3. Microscopic examination showed that the uterus, cervix, ovaries and fallopian tubes and gall-bladder tissues did not indicate any evidence of malignancy.
4. The sections were taken from the Leiomyoma tissue (fibroid) and the uterus. The myometrium revealed a cellular spindle shaped tumour with neo-plastic cells arranged in sheets and fascicles. The cells displayed characteristics suggestive of focal increased cellularity, nine-ten mitosis/ten HPF and the tumour showed a prominent myxoid change. There is no mention of invasion into adjacent tissue or vascular invasion, which are strongly indicators of malignancy.
5. IHC was carried out after which an impression (not diagnosis) was given– compatible with leiomyosarcoma (myxoid), grade-II. No equivocal diagnosis of sarcoma was made. The microscopic findings were at that time seemed to be clinically compatible malignancy.

It is clear that Max Hospital did not review the slides which had been prepared at MoolchandKhairati Ram Hospital. The Max Hospital, in-fact, had had prepared fresh slides out of the blocks made available and as such this constitutes a great variation of the specimen sample for the investigation. For better appreciation of this, she would like to elaborate on the diagnostic techniques and interpretation. She says that the macroscopic examination entails the following broad approach :-

1. Relative examination of the tumour tissue with the normal tissue sample, which was not available in this case, as the specimen was received piecemeal.
2. Microscopic examination of cell under low power setting to give an overall picture of the cell arrangement and architecture, necrosis or any other pathology.
3. Microscopic examination under high power to observe any, mitotic count, atypia, necrosis and invasions into blood vessels and surrounding normal tissue.

She adopted the same text-book procedure in this case. The normal protocol for histo-pathological investigation of TAH-BSO procedure requires a pathologist to have the entire organs intact with the fibroid issues visualized with its relation intact. In such situations, the pathologist is required to take blocks from each the representative areas involving the normal uterine tissue with the fibroid as well. This procedure enables the pathologist to study the leiomyoma in relation to the myometrium/endometrium for presence/absence of invasions. The specimen received in the instant case was not intact, thereby, giving, no suggestion as to the overall relation to the uterus. The largest fibroid (or fibroids) was/were received ina bucket as multiple pieces of tissue weighing about 01.5 kgs. Random tissue sections were taken for analysis. In addition, representative blocks from theuterus, cervix, bilateral tubes, ovaries and of the gall bladder received separately were also examined. The observations were recorded in the biopsy report. The Test Requisition Form received in the labs, shows the specimen resected and sent alongwith the clinical impression. Any relevant positive/negative findings recorded by the clinician create the clinical context for the pathologist while examining the sample, as histopathology is a subjective field and not an objective one. The information provide in this Test Requisition Form does not indicate any suspicion regarding malignancy. Both gross and microscopy of the specimen received by are recorded. Admittedly, the Max Hospital did not review any of the slides prepared in MoolchandKhairati Ram Hospital. The complainant admitted that that the slides as well as the blocks were handed over to the complainant. No reasons are forthcoming as to why the very slides which formed the basis of the complaint were not reviewed. Considering the nature of the sarcoma, a different section obtained from the blocks, made available, need not be identical or reveal any common histological features. This is for the obvious reason that the sarcoma may be present at a different level. The histo-pathological investigation proceeds on the assumption that it is not possible to examine every minute section of the tissue and sampling is done of random samples. As such there is a real possibility that the incidence of malignancy could be missed out even after applying diligent and vigilant outlook during the investigations. The nature of this tumour also is evident. The changes in cell structures need not always indicate malignancy. These tumours can be variable in their appearance and features of malignancy like atypia, necrosis and mitotic count, may be focal is written in standard taxbooks and publications (relevant extracts from Ackermans Book of Surgical Pathology-“Smooth Muscle Tumours of the Uterus, published in Arch Pathol Lab Med, Vol-132, April, 2008-Review article published in Oncology research and Treatment titled “Uterine Leimyosarcoma”, 2018-myxoid leiomyosarcoma of the uterus, Am J Surg Pathol, March, 2016-Vol-40). One of the distinctive features of leimyosarcoma is that it appears as solitary mass in 50-75% cases (Ref Blaustein’s Pathology of the Female Genital Tract). The radiology investigations of the deceased; however, noticed several fibroids and the same was recorded in the histopathology report. The fibroids are easily resectable, but sarcomas are infiltrative and would not have been resectable by the surgeon and would have been very evident per-operatively and the same would have been conveyed to the pathologist in the Requisition Form. There is a vast different in the gross appearance of a sarcoma Vs a fibroid. The latter are firm, white, can be separated from the myometrium; whereas sarcomas are reddish, soft, are not separable from the adjacent myometrium. She (Dr. Shashirekha) was aware of the difference while documenting the gross findings. These observations are recorded. She is well aware of the difference between a benign leiomyoma (commonly known as fibroid) and a malignant one (leiomyosarcoma). The points to be considered for the diagnosis, the difficulties encountered and the grey areas are stated in standard text-books. All the factors stated in standard text-books, were considered alongwith the clinical history provided to arrive at the diagnosis.

She further averred that the specimen of the uterus, cervix, bilateral tubes and the ovaries with degenerating fibroids was received on 26thOctober, 2015 at 06.30 p.m. and examined as per the standard guidelines and due care was taken during gross/naked eye examination and microscopy and the report of the biopsy No.2015/1465 was submitted on 30thOctober, 2015 at 03.14 p.m. No atypia was seen in the sections studies and the impression was given as : endometrium-atrophy, mymometrium-leiomyomata, benign, cervix-endocervicitis,-chronic, ovaries (bilateral)-atrophy, fallopian tube(right)-within normal limits and fallopian tube (left)-paratubal cyst(benign). The specimen of gall-bladder was received on 27thOctober, 2015 at 01.21 p.m. and examined as per the standard guidelines and due care was taken during the gross/naked eye examination and microscopy and the report of biopsy No.2015/1466 was submitted on 30thOctober, 2015 at 03.11 p.m.. No atypia was seen. Focal lymphoid follicle formation was seen and the impression was-Gall Bladder-Chronic Calculous cholecystitis. On naked eye examination, there were no features of malignancy (soft consistency, yellow-tan appearance, necrosis, invasion into uterine wall). Invasion into the uterine wall is a strong pointer towards malignancy, which was not there in this case. The said mass was received separately, indicating that it was easily removable from the uterus, indicating its benign nature. The mass received in the lab was firm in inconsistency, white (though piece meal) with few areas of haemorrhage and mucoid appearance at places, but no necrosis-a typical description for a fibroid with degenerative changes (benign lesion). The findings, given by her (Dr. Shashirekha) are duly supported with the medical literature contained in the standard textbooks which guides her that leiomyosarcomas are mostly single. In the present case, there were multiple fibroids, which remained another pointer towards the benign nature. Considering all these points, on naked eye emanation/gross examination, an impression of fibroids was made. The multiple sections were studied from the lesion, alongwith representative sections from the entire specimen provided. The lesion had all features of a benign tumour. There are many features that are required to be taken into the account to differentiate a benign from a malignant leiomyoma. Benign leiomyomatous cells and malignant cells resemble each other and may not be differentiated on their morphology alone. The paints to be considered for the diagnosis, the difficulties encountered and the grey areas are stated in the standard text-books. All the factors stated in the standard text-books, were considered alonwith the clinical history, provided to arrive at the diagnosis(atypia, mitosis, tumour, necrosis and invasion, in which atypia is subjective and mitotic count has poor reproducibility). To reduce the symptoms of pain and bleeding, the patients are often prescribed progesterone, which can increase the mitotic count and the cause haemorrhage in fibroids. But no such history was available in this case, but the same should be considered while doing the mitotic count. No invasion was demonstrated on microscopy-into uterine wall/outside the uterus, ovaries, cervix and fallopian tubes. No invasion into surrounding structures was mentioned in the Requisition Form from the clinician (can be confirmed from the operative notes too). There was no haemorrhage/significant areas of tumour cells necrosis on microscopy and cells resembled benign cells. Consider the gross and microscopic features and knowing that leimyosarcomas arise ‘de novo’ and not from benign uterine fibroids, a diagnosis of benign leiomyomas was made. Thus, the interference drawn by her (Dr. Shashirekha), was based on scientific facts and the observations made and neither, there was any failure in interpreting the nature of fibroid, nor there was any wrong inference/impression drawn.

She also averred that the PET scan and CT report submitted, belongs to a patient by the same name, but aged 63 years, which was not the age of the this patient (Smt. Shashi Batra). Also, the surgery done for the patient included removal of both tubes and ovaries whereas, this CT/PET reports as bilateral adnexa are unremarkable. It is not possible to confirm or accept this report as belonging to the same patient. It is pointed out that the observation in the PET-CT scan report, referring to the possibility of missed leiomyosarcoma of uterine origin needs exclusion, is suspicious and unusual. Even, if these observations are to be assumed to be medically pertinent, it was incumbent for further investigations to be based on the very specimen material subjected to microscopic investigation by the pathologist. As already pointed out, the section samples of tissues from the same block under the microscope can show great variations. The clear indicators of malignancy are not present uniformly in the tissue. It may not even show up in all the specimen slides, prepared at random from the different slides/pieces of the tissue and different. It is pointed out that the alleged recommendations/observations of Dr. Lalit Kumar, suggesting to get the slides/blocks reviewed are significant. The advice was intended to identify, if, there was any pre-existing malignancy at that time of hysterectomy and is a routine advice. It is a significant that the opinion that both the slides and block to be reviewed was recommended to ascertain whether there is a faulty observation by the pathologist while examining the slides or whether these slides actually examined by the pathologist correctly, did not show up any malignancy. Thus, mere examination of a fresh slide prepared from the block without comparing the same with the slide prepared by the pathologist, cannot prove the medical negligence. These opinions cannot be suggestive of any negligence. The report of Rajiv Gandhi Cancer Institute, makes it evident that its report is based on fresh biopsy. The advice or review of slides/blocks in view of the prior history of hysterectomy is as such routine and not suggestive of any misdiagnosis. The report from the Rajiv Gandhi Cancer Institute mentions only possibilities and has not given any equivocal diagnosis. No review was done even at Rajiv Gandhi Cancer Institute. She denied that Max Hospital carried outany detailed review of the slides prepared at MoolchandKhairati Ram Hospital. The averment is completely misleading and deliberate, as evident from the alleged report dated 18thJune, 2016. The specimens examined by the Max Hospital, were not the slides prepared at MoolchandKhairatiRam Hospital, but blocks. The specimens received, were not ten blocks of TAH-BSO alongwith that of the gall-bladder. The report regarding the leiomyoma tissue does not indicate any categorical findings of malignancy. It is further pointed out that this report cannot be relied upon for the reason that the same was prepared post PET-CT scan and as such the pathologist’s interpretation is expected, be based upon correlating it to the scan. There is nothing to suggest that any of the observations made in respect of the leiomyoma tissue give an irrefutable and unquestionable conclusion of the existence of malignancy. The differential diagnosis is a possibility and both the judgments as long as supported by the reasons, do not allude to any suggestion of negligence. The observations are misleading for the following reasons -:

1. Leiomyoma tissue : through the report observes cellular spindle shaped tumour with neoplastic cells in sheets and fascicles. This by itself does not indicate sarcoma. Focal increased cellularity with mild to moderate focal pleomorphism is also not a conclusive indicator of malignancy.
2. Mitosis values given are below text-books values to suggest malignancy.
3. The finding and the observation about the prominent myxoid change is inconsistent with the other observations. Myxoid tumours are not cellular (they are hypocellular).
4. Thus, myxoid tumours would show large areas of myxoid changes with few cells. The observations are, therefore, inconsistent.
5. Eosinophlc changes with ghost luclei, as recorded, also need not be conclusive evidence of maligancy. This feature, which is also known as Tumour Cell Necrosis (TCN), is subject to inter-observe difference and there is no one hundred percent concordance between pathologists regarding this feature. In the uterine leiomyosarcomas (Interobserr variability in the interpretation of tumor cell necrosis, Am J of Surge Pathol, 2013, May; 37(5):650-8).

Further, the said report was prepared in the back drop of PET scan and fresh biopsy(done 3at Rajiv Gandhi Cancer Institute) and, therefore, the pathologist had enough material to correlate any otherwise insignificant microscopic observations with a diseased condition. Thus, the report of Max Hospital cannot be treated as proof of medical negligence on the part of the pathologist. It is respectfully submitted histo-pathology is a subjective evaluation and has its own inherent limitations. The difference of opinion in perception of things cannot be ruled out in toto; since, the histopathology diagnosis is not mathematics where two plus two always make four. Interpretations by the individuals do bring in different opinions, but such difference of opinion does not amount to negligence in all the cases. The some ethical issuesinhisto-pathology, R F Chinoy, Indain Journal of Medical Ethics, Vii (2), April-June 200 mentions. This article also states that “it is importantto appreciate the strengths as well as the inherent weakness in the science-an art of histopathology. Histopathology is basically learning the language of cells, interpreting patterns of tissue withina given specific clinical contacts. Outside the world of pathologist, there is only a dim understanding of the truly subjective nuances innate to this discipline. Some clinicians tend to equate a histopathology diagnosis with a mathematical formula providing predictable and consistent answers. They do not accept any leeway for inter-observer variation in pathology. Such clinicians must understand that a difficult case is similar to interpreting a semi-abstract work of art. Different people looking at the same picture come up with a different and often divergent interpretations.” In medical terminology ‘Grade’ and ‘Stage’ are different concepts. For reasons not known to her, the Max Hospital’s report has graded the leiomyosarcoma, which is contrary to what has been given in the standards books/guidelines/publications (vide references from-Protocol for Examination of specimen from Patients with Primary sarcoma of the Uterus “by College of Americal Pathologist; Blaustein’s study of Female Genital Tract; WHO Classification of Tumours Female Reproductive organs, IARC, 4th Ed; Review article published in Oncology research & Treatment titled “Uterine Leimyosarcoma”, 2018. This is because; they are rare and are considered to be aggressive in nature, with poor survival rates, even in early stages.

She further averred that Tata Memorial Hospital graded the deceased (the patient) to grade-III, which is contradictory to what is written in the standard books/references (mentioned) and is medically incorrect, as leiomyosarcomas, they are not graded as per the references submitted. Tata Memorial Hospital suggested a review of the slides, does not have any nexus with any alleged medical negligence or misdiagnosis. The same slides were not reviewed at Tata Memorial Hospital. As pointed out, there could be a great deal of variation in slides, prepared from the same blocks, keeping in mind, the nature of the disease and its spread. Thus, slides, drawn from the same block, can exhibit variations that could be totally contrasting. There is always a well recognized element of uncertainty as to the reliability of microscopic examination. As already pointed out, the cellular abnormalities, as observed in the present case by the pathologist, did not justify drawing any inference towards malignancy. It is again pointed out that for leiomyosarcoma, there is no internationally recognized grading prescribed and as such the allegation that the tissues obtained post-surgery in October, 2015, has proof of grade-II cancer, is completely without any basis. The PET-CT scan report had no nexus with the report, prepared by the pathologist and the attempt to draw a linkage between the two, is far-fetched. It is denied that the failure to detect malignancy in October, 2015, was on account of any medical negligence or want of due diligence. The report prepared, was based on focused examination to identify any indicators that would suggest malignancy. The report shows that a precise visual inspection of the mass and tissue samples received in the lab. The report also shows, representative sections were taken and studied. It is further denied that the patient died due to failed diagnosis by the pathologist (Dr. Shashirekha) or that her treating doctors had adopted treatment strategy with a fatal delay, resulting in the spread of malignancy. The averment is contradictory to available medical literature, relied upon by the complainant himself, which indicates the poor prognosis for the patients with leiomyosarcoma. The complainant admits that at the time of the surgery, the patient already had stage-II cancer. Such patient, even as per medical literature produced, had poor prognosis. Leiomysarcoma is an extremely aggressively kind of sarcoma and as such its spread into the lungs can happen within a short span of time since the origins of the condition are in the myometrium, which are highly vascularised. It, is, therefore, denied that the spread of the sarcoma was in away relatable to any alleged misinterpretation of the cell pathology, investigated by her (Dr. Shashirekha). It is further pointed out that no autopsy was done to verify the cause of death. Even after going to three hospitals, only one biopsy was taken (from the pelvic mass); the lesions in the liver, bone and lungs were not studied. Her (Dr. Shashirekha) role was limited to histological examinations and that she was not part of the team for the treatment of the patient. The histo-pathological reports prepared on the basis of carrying out biopsy and examination of specimen as per prescribed standard guidelines and information, given by the clinician. The radiological investigations done at various times were not compared and reviewed. Both, the patient’s party and the clinician had access to the pre-operative investigations (chest x-ray, USG abdomen, etc.), which were not followed-up. Please refer to pre-operative chest x-ray report done in October, 2015, which forms a part of the case sheet, submitted by the hospital. It is evident from the pre-operative radiological findings that the patient had more than just fibroids. Only an autopsy would have thrown a proper light for the cause of the death.

On enquiry by the Disciplinary Committee Dr. Shashirekha stated that as per the policy of the hospital slides which are made from blocks of the exercised specimens are kept for records in the hospital and the same are not handed over to the patient when a review of the exercised specimen for histopathological examination is required; only blocks are given for purposes of review of histopathological examination. In this case also only blocks were handed over to the patient and not the slides.

In view of the above, the Disciplinary Committee makes the following observations:-

1. The patient Smt Shashi Batra, a 53 year old female, was admitted in Moolchand Khairati Ram Hospital on 25-10-2015 under Dr. Anil Malik with complaints of bleeding per vagina, mild pain in RHC since two months with cholelithiasis. There was no history of anorexia or weight loss. The CECT done revealed cholelithiasis with large Fibroid uterus. She underwent the surgical procedure of laparascopic cholecystectomy with laparoscopic adhesiolysis with Total Abdominal Hysterscopy with Bilateral Salpingo-oophorectomy on 26-10-2015 under general anesthesia. The surgery was uneventful and the patient was discharged on 29-10-15. The Biopsy report no.2015/1465 dated 30-10-2015 of Moolchand Khairati Ram Hospital, of the specimen: uterus, cervix, bilateral tubes and ovaries with degenerating fibroids; reported by Dr. Shashirekha, pathologist, gave the impression :- (1) Endometrium- Atrophy (2) Myometrium- Leiomyomata benign (3)Cervix- Endocervicitis, chronic (4) Ovaries (Bilateral)- Atrophy (5) Fallopian tube ( Right) – within normal limits (6) Fallapion tube (left)- Paratubal cyst (benign).

As per the complaint in month of May 2016, the patient experienced continuous coughing symptoms and she underwent chest x-ray at Dr. Mishra’s X-ray and Ultrasound Clinic which vide report dated 6-06-16 reported multiple well circumscribed rounded shadows (like Cannonball) and observed that possibilities of Secondaries should be strongly considered and suggested CECT for further evaluation and confirmation. The patient, thereafter, underwent Whole Body PET CECT scan which vide report dated 8-06-16 revealed *Hypermetabolic active disease involving – Bilateral pulmonary nodular masses with left pleural effusion; Right lobe hepatic parenchyma lesion; D-11 vertrebral lesion; pelvic mass lesion, abutting and inseparable from vaginal vault; findings suggestive of underlying malignant pathology(possibly sarcomatous) in present clinical context, possibility of missed Leiomyosarcoma of uterine origin needs exclusion; suggested biopsy and IHC correlation.* The patient then consulted Dr. B.R.A., IRCH, AIIMS, New Delhi on 09-06-16 where she was diagnosed as suspected case of leomyosarcoma uterus (Metastic) lungs and advised Block review as well as ultrasound guided biopsy from vaginal vault. A fresh biopsy (Biopsy no.B/4947/16) and IHC conducted at Rajiv Gandhi Cancer Institute and Research Centre, Rohini vide report dated 17-06-16 gave the opinion of *suspected metastasis of mesenchymal tumor with a possibility of Leiomyosarcoma endometrial stromal sarcoma and in view of prior history of hysterectomy advised to review the slides/blocks for the primary.*

The Blocks and slides of the specimen excised at Moolchand Khairati Ram Hospital *viz: 10 blocks of TAH and BSO alongwith gallbladder biopsy (9 blocks),* were reviewed at Max Super Speciality Hospital, Saket and vide Histopatholgy no. S-7319/16 report dated18-06-16 gave the *impression compatible with Leiomyosarcoma (Myxoid) Grade 2.*

The Tata Memorial Hospital on consultation on 8-07-16 also gave the opinion that clinical behavior suggestive of grade-III leiomyosarcoma extensive disease (+).

As per the complaint, the patient underwent 6 chemotherapy sessions from June 2016 to November 2016 at Max Hospital Saket and thereafter, expired on 24-11-2016.

1. It is observed that the blocks of the specimen (Biopsy no. 2015/1465 of Moolchand Hospital as provided by the complainant), were subjected to histopathology examination by the Expert Member of the Disciplinary Committee. As per the Expert Member multiple sections examined show a spindle cell tumour with cells arranged in intersecting fascides with focal areas of hemorrhage. The tumour cells are showing moderate pleomorphism; frequent mitotic activity is seen in two of the slides (9-10/10HPF); there is no evidence of necrosis.

Impression: Smooth muscle tumour of uncertain malignant potential (Stump). Possibility of leiomyosarcoma cannot be ruled out given the limitation of sampling.

It is thus evident that the initial biopsy from Moolchand Khairati Ram Hospital did not identify leiomyosarcoma, which was later confirmed by subsequent reviews and imaging. The final diagnosis of leiomyosarcoma suggests that the initial histopathology may have missed the malignancy.

1. It is apparent that Dr. Shashirekha did not exercise due diligence whilst undertaking and preparing the histopathological examination of Biopsy no. 2015/1465 which was expected of ordinary prudent pathologist, as both the review of the bloc section (Biopsy no. 2015/1465) done at Max Super Speciality Hospital, Saket and by the Expert Member of the Disciplinary Committee conclude that the blocks review, was compatible with leiomyosarcoma/stump.
2. The delay in accurate diagnosis may have impacted the treatment options and prognosis, as leiomyosarcoma typically requires different management compared to benign Leiomyomata.
3. In our considered opinion it is highly unlikely that a section of a block of a specimen subjected to histopathological examination will be bereft of Mitotic activity if the rest of most of the portion of the block showed significant Mitotic activity.

In light of the observations made herein-above, it is the decision of the Disciplinary Committee that the name of Dr. Shashirekha (Delhi Medical Council Registration No.17060) be removed from the State Medical Register of the Delhi Medical Council for a period of 30 days with a direction that she should be more careful in future.

Matter stands disposed.

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