



STP-I

Society of Toxicologic Pathology-India

NEWSLETTER JANUARY 2020

EDITORIAL

Central council of STP-I is wishing the members a Very Happy and Prosperous New Year 2020. We are pleased to meet the members through this newsletter. To summarize our activity in the year 2019, we had conducted two workshops, one webinar and IBTP examination. The committee is actively working towards our 2020 conference and successful in identifying international/national speakers, fixing venue and started getting commitment from sponsors. The content of this newsletter includes STP-I bi annual conference update, note about perspectives and challenges in preclinical toxicology, a case report and update from IBTP registrar.

EDITORIAL TEAM,

Dr. P. Kalaiselvan - Editor

Dr. Sowmya Bharath – Associate Editor

Dr. M.R. Balaji - Member

MESSAGE FROM GENERAL SECRETARY

STP-I Bi annual Conference Update.

As you are aware, STP-I conducts its conference bi annually. This year conference will be held on October 30, 31 and November 1, 2020. This year's conference will be held again in Hyderabad at Marigold Hotel.

The organizers of 2020 conference have put together some hot areas of current interest to Toxicologic Pathologists and Toxicologists. The theme of conference is **Eighth conference and Continued Education Program on 'Toxicologic Pathology of Sensory Organs, Medical device and Digital Pathology'**. We have invited national and international experts in the respective field to cover all of the above interesting topics. Currently all the logistics are being worked out to make the conference a grand success. We anticipate over 250 participants who are Toxicologists and Pathologists attending this conference. Please watch out for more announcements on the progress of the conference in the coming weeks and months.

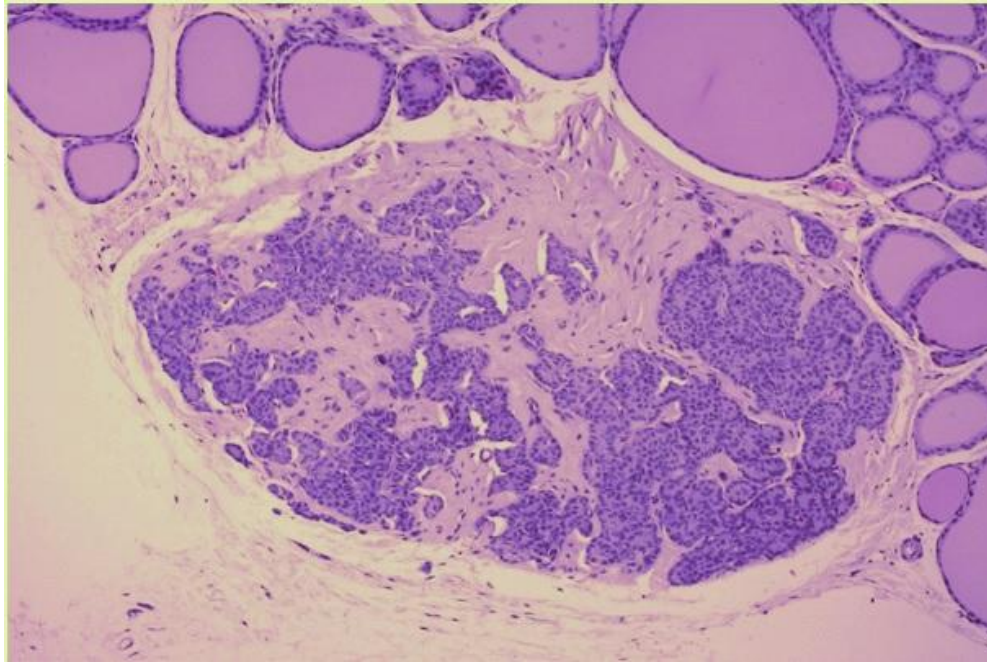


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WHAT'S YOUR DIAGNOSIS?

Photomicrograph of parathyroid from a control female rat in a 90 day oral sub-chronic study administered with analytical grade water. What is your diagnosis? Visit page 8 for answer !!!



10x magnification. H&E staining



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Pre-clinical Toxicology in the 21st century : Perspectives and Challenges

Dr. Madhav Marathe,

Vice President, Pre-clinical Toxicology and Peer Review Pathologist,

Sun Pharma Advanced Research Co. Ltd. Sun Pharma Road, Vadodara-390 020.

All new chemical entities (NCEs) or prospective new drugs or new formulations have to undergo a battery of Standard pre-clinical safety evaluation studies (traditionally called as Toxicology Studies). These studies comprise of at least 20 odd studies starting from a single dose acute studies in rodents and repeat dose studies of 14, 30 or 180 days in rodents and non-rodents and a 270-day study in dogs or monkeys with toxicokinetic (TK) studies. These studies help to determine a safe starting dose in the phase- I, II, III and IV clinical trials. Further to evaluate safety in women of child bearing age, Developmental and Reproductive Toxicity (DART) studies and a recent addition of male fertility studies are done including mutagenicity studies and toxicity studies in Juvenile animals is a new challenge.

In 21st century, we may have to adapt new challenges by working with a combination of softwares, digital pathology e.g. Insilico toxicology, BCOP (bovine corneal opacity) and skin draft test, that would replace eye/skin irritation testing in rabbits. These tools may cut down cost and time required from concept to market and reduction in animal usage in toxicology studies.

A new requirement is to implement a 7 sections of Brain for histology evaluation, instead of traditional traditional 4 sections. It would be a real challenge for pathologists and also to digital pathology development in this organ. In carcinogenicity study, a 2 year study in mice is reduced to a 6-month study, by using genetically modified strain of mice. It thus reduces the animals required as this study, use only half the number of mice, than used in traditional 2 year study. Thus it saves time, money and 50% mice.

Even submission of data is no longer a paper data but all data are submitted via e-data referred as SEND (Standards for Exchange of non-clinical Data). Histopathology findings, have to be described as per INHAND (International Harmonisation of Nomenclature and Diagnostic Criteria) document. Hitherto, peer review of histopathology of organs was optional, but now it is mandatory to conduct peer review of all organs in at least 30% of study animals and if there is a target organ of toxicity, then peer review to be extended to target organ/s of all dose groups and including recovery groups. There is an OECD guide-line for how to conduct and who should/can conduct a peer review.

Very recent and novel tool is being developed to digitalise histology images, that would include diagnosis into normal vs not-normal. So the pathologists would have to examine the tissues only from not-normal basket. It would again save time and cost. Two more tools are under



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development: One is for digital assessment/diagnosis of bone marrow cells into M:E ratio and second one to digitally identify 14 stages of spermatozoa development till maturation. Digitalisation would soon be storming into the bastion of safety evaluation stages/studies and convert those into digital form and/or e-data or insilico models.

Toxicology studies are required to be conducted as per Good Laboratory Practices, documented and are audited by Quality Assurance Unit. Any or all studies could be audited by US FDA, EU or OECD inspectors on need basis or occasionally a surprise audit is also conducted by these agencies.

MESSAGE FROM REGISTRAR IBTP

Dr. Shekar Chelur

Indian Board of Toxicologic Pathology established in 2011 is an affiliate of Society of Toxicologic Pathology – India. The objective of the Board is to encourage the study of the science of toxicologic pathology and its allied fields; to stimulate the advancement of existing standards for professional practice; to prepare and administer procedures, including testing, for the recognition of such standards by certification for those members of the profession who, measured against such standards, demonstrate competence deserving recognition as “Diplomates of the Indian Board of Toxicologic Pathology”. The current boards members include President: Dr. S. K. Vijayasarithi, Vice President: Dr. Venkatesha Udupa, Board members: Dr. Kamala Kannan, Dr. Prabhu P.C., Dr. Jomy Jose, Dr. Nataraj G.J. and Registrar: Dr. Shekar Chelur

Board certification examination is being conducted yearly since 2012 and till date 43 experienced toxicologic pathologists have passed the examination and qualified as “Diplomate of Indian Board of Toxicologic Pathology” (DIBTP). Further, 2012 and 2013 batch of diplomates were recertified for additional five years by virtue of their active practice, continued professional development/continuing education and recertification examination.

Two workshops were conducted in year 2019 followed by certification examination. 17th STPI IBTP Toxicologic Pathology Workshop was held during 13-14 April 2019 at Vadodara. Total of 53 participants attended the workshop which had lectures and practicals by senior toxicologic pathologists. Continuing education topics included Female reproductive system by Dr. Pinakin Soni, Male reproductive system by Dr. Shekar Chelur, Endocrine system by Dr. Satish Panchal, Cardiovascular system by Dr. Venkatesha Udupa, Respiratory system by Dr. Ashwin Patel, Integumentary System by Dr. Pavan Patil with general lecture on Preclinical Drug Discovery and Development of Small Molecule Oncology Drugs by Dr. Shekar Chelur



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18th National Workshop on Toxicologic Pathology was held at Bengaluru during 7-9 September 2019. This three day workshop was attended by 46 participants and had lectures and practicals by senior toxicologic pathologists. Continuing education topics included Urinary and female reproductive system by Dr. Kamala Kannan, Male reproductive system and digestive system by Dr. Shekar Chelur, Endocrine, lymphoid and nervous system by Dr. Vijayasarithi, Hepatobiliary system by Dr. Raghul Jayaprakash, Respiratory system by Dr. Ashvin Patel, Cardiovascular system by Dr. Venkatesha Udupa, Clinical Pathology by Dr. Seema Balani and Musculoskeletal system by Dr. Jomy Jose .



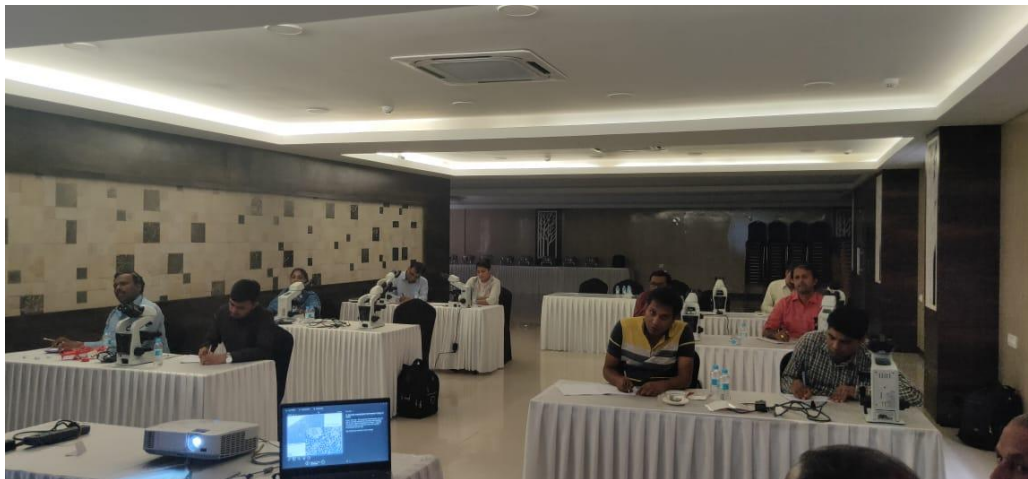


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Indian board of Toxicologic Pathology examination for the year 2019 was held on November 16th, 2019 at Bengaluru. Total of ten aspirants appeared for examination which consisted of one theory examination and two practical examinations.





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NEW IBTP DIPLOMATES

Here is the list of pathologists who passed the 2019 IBTP examination

Dr. Praful Patel

Dr. Somnath Wagh

Dr. Kapil Vachhani

Dr. Madhav Nilakanth Mugale

Dr. Hardik Panchal

Dr. Dharani P

Dr. Akaram Tanaji Bagal

Dr. Rajesh K

Dr. Rajesh Jadav

Dr. Nikita Joshi





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IMPORTANT DATES

- IBTP 2020 exam: 29th October 2020
- STP-I Conference: October 30, 31 and November 1, 2020

INTERESTING WEBINAR LINKS

A pathologist's approach to characterizing the safety profile of AAV-based gene therapy

Animal models to assess the immunogenicity of AAV vectors

<https://toxpath.org/web-education.asp>

WHAT'S YOUR DIAGNOSIS?

Fibrosis of parathyroid gland.

Diagnostic Features:

- Increased amounts of mature collagen in the capsule or interstitium of the gland.
 - Fibroblasts are usually not prominent.
- Pathogenesis/cell of origin: Collagen deposition by fibroblasts following inflammation, necrosis, or hemorrhage.
- Incidence: 0.98%

References:

Annamaria Brändli-Baiocco et al, 2018, Nonproliferative and Proliferative Lesions of the Rat and Mouse Endocrine System, Toxicol Pathol 2018; 31 (3 Suppl): 1S–95S

Historical control data on non-neoplastic findings in Wistar rats. (Compiled from bioassays performed at RCC Ltd. Itingen/Switzerland)

Case contributed by:

Sowmya Bharath, Amod Kale, Narendra Deshmukh, Mukul Pore, INTOX PVT LTD, PUNE



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COMMITTEE MEMBERS

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Dr. Nikita Bhatt, M. V. Sc

Members' contribution:

*Hereby we are inviting
members to contribute to
newsletter by sending article,
what's your diagnosis etc. to*

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