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Short Communication

A New Dimension in Ensuring Safety of Laser and Light-Based Devices in Dermatological Practice- Materiovigilance Programme

C Deepalatha[1*], Vivekanandan Kalaiselvan[2], Akshay[3], Shubhang Arora[4], Nikita Mishra[5]

[1]Professor and Head, Department of Pharmacology, Coordinator- Pharmacovigilance, Materiovigilance Centre, Mamata Academy of Medical Sciences, Bachupally, Hyderabad, India

[2]Senior Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad, India

[3]Assistant Professor, Department of Dermatology, Mamata Academy of Medical Sciences, Bachupally, Hyderabad, India

[4]Managing Director, Yashoda Hospitals, Ghaziabad, India

[5]materiovigilance Associate, Indian Pharmacopoeia Commission, Ghaziabad, India

***Correspondence author:** C Deepalatha, Professor and Head, Department of Pharmacology, Coordinator- Pharmacovigilance, Materiovigilance Centre, Mamata Academy of Medical Sciences, Bachupally, Hyderabad, India; Email: c.deepalatha@gmail.com

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Abstract

Introduction of LASERS and their applications have given new multiple dimensions for less invasive, more precise and effective treatment of skin lesions with some adverse events following treatment in clinical practice of Dermatology. They are source of electromagnetic radiation with applications for cutting, destruction, coagulation or restoration of skin tissues. The main objective of this study is to bring in more of awareness about technical and practical hinderances expected during application of Lasers for ensuring effective management while treating skin lesions. As Indians they have more dermal melanin content are prone for skin injuries and complications subjected to light-based devices treatments, which may lead to permanent sequelae. Prioritizing safety of patients before, during and after treatment following adverse events, to follow certain standard guidelines and timely reporting of adverse events while using medical devices to Materiovigilance Programme of India cell for improving more effective treatment for better patient treatment outcome with quality health care treatment approach. Clinicians who are treating with lasers must have complete knowledge on usage of devices and their adverse events, to follow standard protocols for quick action and timely treatment of patients and timely reporting to Bio medical Engineering department for correction of devices. Regular conduction of sensitization and awareness programmes to all healthcare professionals to notify and report to Medical Device Monitoring Centres for effective implementation of Materio-vigilance Programme of India.

Keywords: Lasers; Skin Complications; Materiovigilance; Medical Devices; Adverse Events

Introduction

Dermatological practice has recently expanded to include the use of sophisticated medical devices for various indications. LASER (Light Amplified by the Stimulated Emission of Radiation) light waves are excellent for precise surgical applications but also for targeting specific tissue types [1]. Medical procedures using laser therapy and light related devices are used for the treatment of hair removal, telangiectasia removal, photo rejuvenation, acne scar reduction, tattoo removal and pigmentary disorders [2]. Medical device related adverse event monitoring plays a significant role in reducing adverse events due to Laser therapy and Light related devices. Adverse events associated with laser surgery including burns, blisters, pain and scarring. To monitor the safety and ensuring quality of medical devices used in the country, Ministry of Health and Family Welfare, Government of India approved and commenced Materiovigilance Programme of India (MvPI). Materiovigilance programme was launched by the Drugs Controller General of India DCG (I) on 06 July 2015 at Indian Pharmacopoeia Commission (IPC), Ghaziabad Since 2018.

IPC functions as National Coordination Centre (NCC) for Materiovigilance programme. IPC is an autonomous institution under Ministry of Health and Family Welfare, Government of India [3]. The programme is also supported by the collaborating organization; Sree Chitra Tirunal Institute of Medical Sciences (SCTIMST), Thiruvananthapuram acts as the national collaboration centre, National Health System Resource Centre (NHSRC), New Delhi acts as a technical support centre and provide support to the programme and Central Drugs Standard Control Organization (CDSCO), New Delhi is the National Regulatory Authority (NRA) of India. In India, medical devices are regulated by the Medical Device Rules (MDR), 2017 and is effective since January 1, 2018. Materiovigilance program aims to improve Indian patient safety by enhancing the adverse events reporting practice and developing more evidence-based recommendations to CDSCO or creating a regular advisory for healthcare professionals or to the general public regarding the safety surveillance of medical devices. Under MvPI, various modalities to report adverse events associated with medical devices have been developed. These modalities include an editable medical device adverse event reporting form, a toll-free helpline number (1800-180-3024) and a field safety corrective action form to notify the regulatory authority and healthcare professionals on corrective actions or recall by the manufacturer. In quo of Coronavirus disease 2019 (COVID-19) pandemic, one-page editable form has been developed to enhance the adverse event reporting of Personal Protective Equipments (PPEs). This article highlights various types of lasers used in cosmetic dermatology, adverse events reporting and its management, role of interprofessional team in evaluating such adverse events related to laser devices. Detection of adverse events and immediate therapy are vital to avoid permanent sequalae. We review adverse events that occur during Laser procedures, reporting to medical device adverse event monitoring centres and their management. Laser complications are defined as any undesirable effects that occurs with Laser treatment even if expected. It is mandatory that Laser physicians be familiar with basic principles of Lasers, Laser -Tissue interactions as well as device being used in order to minimize complications. Laser device related adverse event detection and reporting results in more effective and safer treatment outcomes. Laser physicians need to update themselves about Materiovigilance program to establish scientific validity between laser devices and adverse events as these devices produce new and unfamiliar adverse events [4].

Lasers commonly used in Dermatology

1. Q-Switched ND-YAG laser- Pigmentary disorders
2. Fractional Carbon dioxide lasers
3. Erbium Yag laser
4. Intense pulsed light - Hair Reduction
5. Pulsed Dye lasers - Vascular Lesions
6. Ultrasound based device - Body Contouring

Adverse events of laser procedures have classified into immediate (up to 7 days), transient (1-6 weeks), persistent (after 6 weeks) [5-8].

Immediate

1. Erythema
2. Burning sensation
3. Edema
4. Pain
5. Blistering
6. Petechiae

Transient

1. Post-inflammatory hyperpigmentation
2. Post- inflammatory hypopigmentation
3. Acneform Eruptions - Post laser hair reduction
4. Petechiae
5. Leukotrichia
6. Reactivation of HSV infection

7. Compartment syndrome after tattoo removal
8. Tattoo granuloma

Persistent
1. Post-inflammatory hyperpigmentation
2. Post- inflammatory hypopigmentation
3. Scarring
4. Leukotrichia
5. Tattoo granuloma

Management
Management of medical device associated adverse events depends on the type of seriousness and the details of adverse events. Immediate mild reactions can be managed by cool gel packs.

Moderate to severe reactions require both topical steroids and anti-inflammatory agents.

Transient and Persistent
1. Post-inflammatory hyperpigmentation - Use of topical skin lightening agents such as kojic Acid, Arbutin, Azelaic Acid can be done.9 Chemical Peeling also can be done in severe cases
2. Post inflammatory hypopigmentation- Application of 65% trichloroacetic acid, Phototherapy [10]
3. Acne form eruptions - Oral doxycycline for 10-20 days and Topical Antibiotic creams [11]
4. Leukotrichia - Eletrolysis

Device Factors Influencing the Occurrence of Adverse Event
Beam profile of the laser machine- devices with a Gaussian beam profile is more prone to adverse events than compared to those a with a Top hat beam profile.

Patient dependent factors such as the type of lesions, its depth, skin type of the patient assessed by Fitzpatrik Skin Variant score,12 compliance have an impact on complications. Type 1 and Type 4 hypersensitivity patients were more prone to pigmentation.

Precautions
1. Avoid sun exposures
2. Avoid friction (Rubbing of skin)
3. Application of mild potent topical steroid with antibacterial agents for 3 days
4. To minimize post procedure complications: All topical application drugs or cosmetics to be avoided

The reporting of adverse events through medical device adverse events reporting forms, detecting temporal association between device and event, establishing causality assessment and root cause analysis helps to minimize further adverse events. Biomedical engineers working in hospitals plays a major role in identifying root cause of problem related to medical device and further necessary action can be initiated. By communicating it with manufacturer for correction. Medical Device Adverse Event Monitoring Centres (MDMCs) are the hospitals/institutions recognized under Materiovigilance programme of India. So far, NCC-MvPI has recognized 293 MDMCs pan India. In MDMCs, healthcare professionals including doctors, nurses, pharmacists, biomedical engineers, etc. should sensitize about the reporting of near miss incidents, serious and non-serious adverse events [13]. If healthcare professionals encounter any adverse events related to medical devices, their responsibility is to forward it to MvPI [14]. Hence, continuous sensitization, awareness programmes and Induction cum trainings are mandatory to attend for dermatologists and cosmetologists working on laser therapy to identify adverse events due to laser devices to establish scientific validity between device and event as to minimize risk associated with laser devices [15-17].

General Considerations

Patient should be educated as to what is to be expected after the procedure and has to report back immediately if any untoward reactions are suspected. Adequate priming with sunscreen, topical retinoids and topical depigmenting agents such as kojic acid, glycolic acid and arbutin will reduce the incidence of complications, especially post-inflammatory pigmentary changes. The laser physician should insist on frequent follow-ups in the immediate post laser period to detect and manage adverse events. Notification of laser device adverse events should be communicated to all healthcare professionals through Academic Meetings, Hospital Mobile Communication Groups, publications, Social- Media may mitigate the risk associated events.

Recommendations

1. Regular servicing
2. Power (Watts) and Energy (Joules) that has to be checked during servicing
3. Protocol Adherence
4. Laser treatment and procedures should be part of core curriculum/post graduate training
5. Laser operators has to be supervised by a qualified doctor while performing the procedure
6. Laser operators has to be trained and their knowledge has to be assessed before they are employed for the job
7. Laser devices has to procure from a certified manufacturer and certified suppliers
8. Government/Regulatory Authorities should make sure that the medical colleges/hospitals are furnished the laser machines for various indications

Conclusion

A thorough knowledge of basic laser physics, complete understanding of the device in hand, optimal parameter settings, proper methods of laser beam delivery, strict adherence to the standard protocols and early recognition of expected adverse effects and an intuition to look beyond the routine are the keys to a safe trouble-free laser practice. Immediate notification of adverse events by clinicians to MDMCs for reporting, for quick action and timely treatment of patients and bio medical engineering department for correction of device. Conduction of sensitization and awareness programmes to all healthcare professionals to notify and report to MDMCs will provide effective implementation of MvPI.

Conflict of Interest

The authors have no conflict of interest to declare.

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