



International Journal of Pharma and Bio Sciences

ISSN
0975-6299

BLENDING OF TECHNOLOGY AND MODERN DAY MEDICAL BIOMEDICAL DEVICES: AN OVERVIEW

MS .KEERTHANYA RAJESH

PSBB Senior Secondary School, KK Nagar, Chennai, India.

ABSTRACT

Advances in health care reached a pinnacle in a new dimension in the last decade. Blended technology with medicine has escalated the scope of their applications in medical care. Apart from widely heard and discussed robotic surgery, there are many recent computers assisted or sensing devices which are used in day to day life of many patients. They intend to treat chronic diseases and thereby improve quality of life and also useful in many emergency condition. This forum tends to provide a comprehensive coverage of very recent and significant biomedical devices and their unique feature.

KEYWORDS: Biomedical devices, Cephalis, Dexcom , First in class devices , Lifestest , Materiovigilance,



MS .KEERTHANYA RAJESH

PSBB Senior Secondary School, KK Nagar, Chennai, India.

INTRODUCTION

Technology shouldered development of medical care from its rooting; the list ranges from a simple X-ray to modern day magnetic resonance imaging, electrocardiogram to automated defibrillators for arrhythmias, insulin pen to continuous subcutaneous insulin infusion pumps etc. Integration of technology in medicine is inevitable and inseparable, in the last five years there are few first in class biomedical devices has been invented and proving their efficiency in patient care. Many chronic diseases like obesity, cardiovascular diseases, diabetes, migraine etc has now biomedical device based therapy in addition to standard therapeutic management.¹

CEPHALY IN MIGRAINE

Migraine affects almost every ten in hundred individuals. It is chronic headache with recurrences and vigorous at times. In 2013, United States Food and drug administration (US-FDA) approved transcutaneous nerve magnetic stimulation device called cerena for treating acute episode of migraine. The drawback of cerena is, it is not effective before the symptoms of migraine, Cephalis is the first FDA approved medical device to prevent migraine onset. It was granted approval on March 2014 based on its efficiency survey from more than 2000 individuals. It is a small self operated battery device that senses and stimulates trigeminal nerve prevents the spread of migraine signals and hence the symptoms associated with it. Cephalis should be used once in a day for not more than twenty minutes.²

MAESTRO IN OBESITY

The magnanimous prevalence of obesity and its related complications are well known. Ideal drug for obesity is still remains as unmet need. None, of weight reducing pills is devoid of adverse effects. Pills are also not effective in sustain weight reduction after the treatment duration. MAESTRO rechargeable system is the first FDA approved device for obese people with body mass index (BMI) more than 35 kg/m².³ Maestro operates by preventing gastric vagus nerve afferent impulses and tends to induce satiety. The sensing is done by electrodes implanted on abdominal wall. This device was shown to be effective in more than 200 individuals with morbid obesity and found to induce sustainable weight loss for a period eighteen months and more.

LIFEVEST FOR SUDDEN CARDIAC DEATH

Sudden cardiac death due to ventricular arrhythmias is common and needs urgent intensive care. Various spontaneous defibrillators have used for adults but not for pediatric age group until December 2015 when lifevest wearable cardiac defibrillator is approved by FDA panel. Lifevest senses abnormal rhythm and gives an alarm to self adjust the frequency of shocks must be given to defibrillate. This can be worn by a child of eight

years or old. It is undoubtedly a boon device for pediatric patients with a risk of sudden cardiac death.⁴

DEXCOM FOR GLUCOSE MONITORING

Dexcom pediatric glucose sensor monitoring device can be used for Type 1 diabetes patients between 2-17 years. This is implanted abdominal wall with its sensor to measure glucose level and sends output value every 5 minutes. This self tracking of glucose level helps parents of type I diabetes mellitus kids and treating physician to assess the variation pattern in blood glucose to adjust their insulin regimen accordingly.⁵

UROLIFT AND MEDTRONIC FOR URINARY AND FECAL CONTINENCE

These two devices used by patients with urinary and fecal incontinence respectively. UroLift is permanently implanted with male patients with prostatic hypertrophy. UroLift senses the urinary filling in the bladder and assist in voiding difficulties and incontinence of benign prostatic hypertrophy patients. UroLift was granted approval by FDA in 2013 based on recommendations from panel of urologist to supports its efficiency.⁶ Medtronic is a handheld device got approval recently in 2015 for bowel incontinence patient. This has a server that impedes impulses of sacral nerve and controls distal colon loading and unloading. These two devices has their unique features due to non availability of satisfactory drugs for these two conditions which often embarrassing for patients and significantly affects their quality of life.⁶

ADR ANDROID MOBILE APP FOR SAFETY REPORTING

Indian IT sector developed ADR mobile app for instant drug adverse reaction reporting.⁷ Conventional adverse drug reaction reporting system though intensified it is often not done a time. Whereas ADR apps enables physicians and other pharmacovigilance reported to submit their suspected adverse drug reaction instantly. This will help to generate a larger database adverse drug reactions reporting in global scenario. These adr mobile apps need a widespread awareness among pharmacovigilance stakeholders to fetch maximum benefits out of it.⁸

CBNAAT FOR MULTIDRUG RESISTANT TUBERCULOSIS DETECTION (MDR-TB)

In March 21, 2016 Government of India introduced cartridge based nucleic acid amplification test to diagnose multidrug resistant tuberculosis at primary health care level. India harbors nearly one third of global tuberculosis infected patients and multidrug resistant TB is a major threat for which regimen is tailor made. Detection of MDR-TB was being done only at few centers before which is decentralized now with advent of

technology. Cartridge based nucleic acid amplification test (CBNAAT) device detects Tubercle bacilli sensitivity within few hours and treatment can be offered accordingly from day one.^{9, 10}

NEW ARRIVALS

Beside aforesaid biomedical devices, axiom neural stimulator system for chronic regional pain syndrome, aspire assist for gastric bypass device for morbid

obesity, cypass aqueous humor drainer for glaucoma, Hepatitis C virus genomic detection devices, Magnetic resonance imaging guided ultrasound device for essential tremor, Xpert Carba-R Assay to detect antimicrobial sensitivity pattern of carbapenem resistant infections are the brand biomedical devices in the last twelve months period and many more are in pipeline which are patient and physician friendly and will be extremely useful in health care system.^{11,12,13,14} Summary of all devices is depicted in table 1.

Table 1
List of biomedical devices and their purpose

S no	Biomedical Device	Function
1	Cephalis	First FDA device to prevent migraine by trans cranial nerve stimulation
2	Maestro	First FDA device to modify gastric vagus nerve to induce satiety feel
3	Lifevest	First FDA wearable pediatric cardiac defibrillator to reduce sudden cardiac arrest
4	Dexcom	First FDA approved pediatric glucose sensing system
5	UroLift	First FDA approved device to sense and modify bladder filling in urinary incontinence
6	Medtronic	First FDA approved device to alter sacral nerve sensation to load and unload colon in fecal incontinence
7	adr Mobile application	First Indian mobile app to enhance adverse drug effect reporting to pharmacovigilance programme of India
8	CBNAAT	First Indian based rapid diagnostic device for tuberculosis
9	Xpert Carba-R Assay	First FDA device to detect carbapenem antibiotic resistance bacteria
10	Cypass	First FDA device to bypass aqueous humor in glaucoma

CONCLUSION

Information technology and computation biology are being used right from drug discovery to patient care therapeutics in clinical practice. Apart from complex machines, patient centric self blood pressure tracking device and glucose monitoring device are those definite great adventures out of biomedical instrumentation and computer assisted information technology systems, even devices has to be monitored, hence at right time when medical devices are being used extensively in India on these days, India launched Materiovigilance programme of India to monitor safety of these devices in last year.¹⁵ Widespread awareness is the need of hour to promote

application of these devices and monitoring services to derive optimal benefits.

ACKNOWLEDGEMENT

Author acknowledges Dr.Krishnan Vengadaragava Chary, Department of Pharmacology, Saveetha Medical College, Chennai for his inputs of my review article.

CONFLICTS OF INTEREST

Conflict of interest declared none.

REFERENCES

1. Medical Device Databases [Internet]. U.S.Food and Drug Administration; [updated 2016 January, cited 2016 August 01] Available from: <http://www.fda.gov/medicaldevices/deviceregulationandguidance/databases/default.htm>.
2. Zach KJ, Trentman TL, Zimmerman RS, Dodick DW. Refractory headaches treated with bilateral occipital and temporal region stimulation. *Medical Devices (Auckland, NZ)*. 2014;7:55-59. doi:10.2147/MDER.S59719.
3. Lebovitz HE. Interventional treatment of obesity and diabetes: An interim report on gastric electrical stimulation. *Reviews in Endocrine & Metabolic Disorders*. 2016;17:73-80. doi:10.1007/s11154-016-9350-7.
4. Knops RE, Kooiman KM, ten Sande JN, de Groot JR, Wilde AAM. First experience with the wearable cardioverter defibrillator in the Netherlands. *Netherlands Heart Journal*. 2012;20(2):77-81. doi:10.1007/s12471-011-0227-9.
5. Laffel L. Improved Accuracy of Continuous Glucose Monitoring Systems in Pediatric Patients with Diabetes Mellitus: Results from Two Studies. *Diabetes Technology & Therapeutics*. 2016;18(Suppl 2):S2-23-S2-33. doi:10.1089/dia.2015.0380.
6. McNicholas TA. Benign prostatic hyperplasia and new treatment options – a critical appraisal of the UroLift system. *Medical Devices (Auckland, NZ)*. 2016;9:115-123. doi:10.2147/MDER.S60780.
7. 2. Mobile App for ADRs Reporting an Effective Tool: [Internet]. Pharmacovigilance Programme of India [updated 2015 December, cited 2016 August 01] Available from: <http://ipc.nic.in/writereaddata/mainlinkFile/File453.pdf>
8. Medical Device Division. Central Drug Standard Control Organization.[Internet] [updated 2016 March, cited 2016 August 01] Available from: http://cdsco.nic.in/Medical_div/medical_device_division.htm.
9. Sharma SK, Kohli M, Yadav RN, et al. Evaluating the Diagnostic Accuracy of Xpert MTB/RIF Assay in Pulmonary Tuberculosis. Goletti D, ed. *PLoS*

- ONE*. 2015;10(10):e0141011. doi:10.1371/journal.pone.0141011
10. Medical devices. Recently approved devices[Internet]. U.S. Food and Drug Administration; [Internet] [updated 2016 January, cited 2016 August 01] Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/default.htm>.
 11. Cortegiani A, Russotto V, Graziano G, et al. Use of Cepheid Xpert Carba-R® for Rapid Detection of Carbapenemase-Producing Bacteria in Abdominal Septic Patients Admitted to Intensive Care Unit. Chaturvedi V, ed. *PLoS ONE*. 2016;11(8):e0160643. doi:10.1371/journal.pone.0160643.
 12. Tato M, Ruiz-Garbajosa P, Traczewski M, et al. Multisite Evaluation of Cepheid Xpert Carba-R Assay for Detection of Carbapenemase-Producing Organisms in Rectal Swabs. Carroll KC, ed. *Journal of Clinical Microbiology*. 2016;54(7):1814-1819. doi:10.1128/JCM.00341-16.
 13. Kumar SS, Wülfing J, Okujeni S, Boedecker J, Riedmiller M, Egert U. Autonomous Optimization of Targeted Stimulation of Neuronal Networks. Jbabdi S, ed. *PLoS Computational Biology*. 2016;12(8):e1005054. doi:10.1371/journal.pcbi.1005054.
 14. Kammer JA, Mundy KM. Suprachoroidal Devices in Glaucoma Surgery. *Middle East African Journal of Ophthalmology*. 2015;22(1):45-52. doi:10.4103/0974-9233.148348.
 15. Materiovigilance Programme of India. Indian Pharmacopeia commission.[Internet].[updated 2016 July , cited 2016 August 01] Available from:<http://ipc.nic.in/index2.asp?slid=408&sublinkid=450&lang=1&EncHid=>.