REVIEW ARTICLE

Impact of Implanted Medical Devices on Patient Quality of Life and Adverse Events: A Comprehensive Review

Davan Basappa Bevoor[1], Mahendrakumar BJ[1], Narayanagowda BS[2]

[1]Department of Pharmacy Practice, Sri Adichunchanagiri College of Pharmacy, Mandya, Karnataka, India,
[2]Department of Orthopaedics, Siddaganga Medical College and Research Institute, Tumkur, Karnataka, India

Abstract

Background: Implanted medical devices (IMDs) are increasingly used to restore, replace, or monitor vital body functions in patients with chronic diseases, offering significant improvements in survival, functional independence, and overall quality of life (QoL). **Objectives:** This review summarizes the major types of IMDs; evaluates device-related, procedure-related, infection-related, immune-mediated, and tissue-interaction complications; and examines their impact on patient-reported QoL outcomes. **Results and Discussion:** Evidence demonstrates that cardiovascular, orthopedic, neurological, sensory, and metabolic implants contribute to improved physical functioning, symptom reduction, and psychosocial well-being; however, challenges such as mechanical malfunction, biofilm-associated infections, hypersensitivity reactions, and long-term device deterioration may compromise safety and clinical success. Patient perspectives captured through QoL tools such as short-form health survey, EuroQol 5-Dimensions, World Health Organization quality of life-brief version, and disease-specific instruments are essential in evaluating real-world outcomes. In addition, materiovigilance systems such as the Food and Drug Administration Manufacturer and User Facility Device Experience Database and the Materiovigilance Programme of India play a crucial role in early detection of adverse events and strengthening post-market device surveillance. **Conclusion:** Integrating clinical performance with patient-centered QoL assessment and robust safety monitoring is vital to maximizing therapeutic benefits while minimizing risks associated with IMDs, and ongoing advances in biomaterials and digital monitoring will further enhance device reliability and patient well-being.

Key words: Adverse events, Device safety, Implanted medical devices, Materiovigilance, Patient-reported outcomes, Quality of life

INTRODUCTION

Brief overview of implanted medical devices (IMDs) and growing use

IMDs are now a major part of patient care because they help support, replace, or monitor different body functions over a long period. These devices include pacemakers, implantable defibrillators, joint replacements, neurostimulators, and many other technologies used to manage chronic diseases. Over the years, improvements in medical engineering and device design have led to a steady increase in their use, as they offer better outcomes and quality of life (QoL) for many patients.[1] With more patients receiving these implants, awareness about device performance and safety has also grown. Reports of device failures and recalls have underlined the need for stronger safety checks, regulatory scrutiny, and careful follow-up after implantation.[2,3] Overall, IMDs continue to transform healthcare, but their widespread use makes continuous monitoring and safety assessment extremely important.

Importance of adverse events (AEs) and QoL as outcomes

Understanding AEs and QoL outcomes is essential when evaluating the real-world performance of IMDs. Since device

Address for correspondence:
Dr. Davan Basappa Bevoor, Department of Pharmacy Practice, Sri Adichunchanagiri College of Pharmacy, Mandya, Karnataka, India. Phone: +919980620269.
E-mail: davanbevoor27@gmail.com

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failures, malfunctions, or complications can significantly affect patient safety, tracking AEs helps identify potential risks early and strengthens post-marketing surveillance systems.[4,5] IMDs are designed to improve health, but unexpected device issues, such as lead fractures or electronic failures, can impact both clinical outcomes and patient well-being, making continuous monitoring critical.[5] Alongside safety, QoL assessments provide valuable insight into how an implant influences a patient's daily functioning, emotional well-being, and overall health status. Tools such as the short-form health survey (SF-36) and World Health Organization quality of life-brief version (WHOQOL-BREF) capture these broader dimensions of health, helping clinicians understand benefits beyond clinical measures alone.[6,7] Together, AE monitoring and QoL evaluation offer a more complete picture of device effectiveness and patient-centered outcomes.

Need for understanding device safety and patient-reported outcomes (PROs)

Traditional clinical measures, such as survival rates or device functionality, often fail to capture the patient's day-to-day experience after receiving an IMD. PROs provide important insights into aspects such as pain, mobility, emotional well-being, satisfaction, and overall daily functioning, offering a more complete picture of real-world device effectiveness.[8,9] Combining PRO assessments with monitoring of AEs allows healthcare providers and researchers to identify potential safety concerns while also understanding the broader impact of devices on patients' QoL.[6,7] Consequently, regulatory bodies recommend integrating PRO data into post-marketing surveillance programs to ensure that both clinical performance and patient-centered outcomes are adequately evaluated.[4]

TYPES OF IMDs AND THEIR INDICATIONS

Cardiovascular implants

Cardiovascular IMDs include pacemakers, implantable cardioverter-defibrillators (ICDs), coronary stents, cardiac resynchronization therapy (CRT) devices, and bioprosthetic heart valves. These devices are used to manage arrhythmias, prevent sudden cardiac death, maintain coronary artery patency, and improve cardiac function in patients with heart failure.[10,11] Pacemakers correct bradyarrhythmias by regulating heart rhythm, whereas ICDs protect against life-threatening tachyarrhythmias. Coronary stents preserve vessel patency following percutaneous coronary interventions, and CRT devices enhance ventricular synchronization to improve cardiac output and functional status.[12,13] Collectively, these cardiovascular IMDs significantly improve survival, exercise capacity, and overall QoL for patients with cardiac disorders.

Orthopedic implants

Orthopedic implants, including hip and knee arthroplasties, spinal fixation devices, and fracture-fixation systems, are widely used to manage osteoarthritis, trauma, spinal degenerative conditions, and osteoporosis-related fractures. Joint replacement surgeries effectively relieve pain, restore mobility, and improve long-term QoL.[14,15] Continuous improvements in prosthetic design and biomaterials have enhanced implant longevity and reduced revision rates. Recent innovations, such as advanced surface coatings to improve osseointegration and reduce infection risk[16,17] and additively manufactured porous implant designs to minimize stress shielding and enhance bone integration,[18] further contribute to safer, more durable implants and better functional outcomes for patients.

Neurological implants

Neurological IMDs include deep brain stimulators (DBSs), spinal cord stimulators (SCSs), and vagus nerve stimulators. DBS modulates abnormal neural circuits to improve motor symptoms in patients with Parkinson's disease and essential tremor, providing substantial functional benefits.[19,20] SCS offers effective relief for chronic neuropathic pain that is unresponsive to conventional medical therapy, reducing reliance on medications and improving daily functioning.[21] By alleviating symptoms and enabling greater independence, these neurological implants significantly enhance QoL for patients with movement and pain disorders.

Metabolic/endocrine implants

Metabolic and endocrine IMDs include insulin pumps, closed-loop/artificial pancreas systems, and implantable continuous glucose monitoring (CGM) devices. CGM technology has been shown to significantly improve glycemic control and reduce hypoglycemia in patients with type 1 diabetes, as demonstrated by Tamborlane *et al*.[22] in the *New England Journal of Medicine*. International consensus recommendations by Battelino *et al*.[23] further highlight the role of CGM in optimizing time-in-range and daily glucose stability. In addition, closed-loop insulin delivery systems, often referred to as artificial pancreas systems, have demonstrated improved metabolic outcomes and reduced treatment burden, as evidenced by Brown *et al*.[24] Collectively, these devices support better metabolic stability, greater daily flexibility, and improved QoL for individuals with diabetes.

Sensory implants

Sensory IMDs primarily include cochlear and retinal implants. Cochlear implants restore auditory perception in individuals with severe-to-profound sensorineural hearing loss by

directly stimulating the auditory nerve. Clinical evidence shows significant improvements in speech recognition, communication ability, and overall social and educational functioning.[25] Retinal implants, such as epiretinal and subretinal prostheses, provide partial visual restoration for patients with end-stage retinal degenerative diseases. These devices stimulate remaining retinal neurons to create light perception and pattern recognition, leading to measurable gains in mobility and functional vision.[26] Overall, sensory implants play a crucial role in restoring independence and enhancing QoL in patients with sensory deficits.

Biocompatibility and material characteristics

The performance and safety of IMDs are closely linked to the biocompatibility and stability of the materials used. Metals such as titanium and cobalt–chromium alloys, as well as advanced polymers and bioresorbable materials, are selected to minimize toxicity, corrosion, and degradation within the body. Biocompatibility depends on the dynamic interactions between implanted materials and host tissues, which ultimately influence inflammation, device integration, and long-term AE risk.[27] In addition, the emphasis that the foreign body response, characterized by macrophage activation and fibrous capsule formation, is a critical determinant of implant longevity and functional performance, underscoring the central role of materials science in safe device design.[28]

AEs ASSOCIATED WITH IMDs

Device-related AEs

Device-related AEs arise from issues such as mechanical malfunction, premature battery depletion, material wear, or structural failure of the implant. In cardiovascular devices, ICD systems may experience lead fractures or generator-related problems, while pacemakers can show variability in long-term battery and hardware performance.[1,7] Coronary stents still carry a risk of stent thrombosis, particularly in complex lesions or in the presence of inadequate endothelialization. Orthopedic implants commonly encounter complications such as wear particle-induced osteolysis, aseptic loosening, and eventual implant failure, which often necessitate revision procedures.[29] These device-specific failures can significantly impact patient safety, functional recovery, and overall clinical outcomes.

Procedure-related AEs

Procedure-related AEs arise during the surgical implantation of devices and include bleeding, infection, vascular or tissue injury, anesthesia complications, and early post-operative pain. Cardiovascular device implantation carries risks such as lead- or catheter-related vascular perforation, cardiac tamponade, or arrhythmias due to manipulation during lead placement. In the orthopedic context, implant surgeries such as hip or knee arthroplasty may lead to perioperative fractures, dislocation, wound complications, infection, or mechanical instability, depending on surgical factors, including the surgical approach and patient comorbidities.[30,31] Early-postoperative AEs significantly influence immediate recovery, prolong hospitalization, delay rehabilitation, and may increase the need for re-intervention or revision surgery.

Infection-related events

Infections associated with IMDs commonly include pocket infections, catheter-associated infections, prosthetic joint infections, and biofilm-mediated device colonization. *Staphylococcus aureus* and *Staphylococcus epidermidis* are the predominant pathogens involved.[32,33] Biofilm formation on implant surfaces further complicates management because bacteria within biofilms show enhanced tolerance and resistance to antibiotics.[34,35] Due to the limited efficacy of antimicrobial therapy against biofilm-embedded organisms, many device-related infections require complete implant removal to achieve a definitive cure.[36,37]

Immune and allergic reactions

Immune and allergic reactions arise when patients develop hypersensitivity to metals commonly used in orthopedic and cardiovascular implants, including nickel, cobalt, and chromium. Evidence shows that metal hypersensitivity can manifest as dermatitis, chronic inflammation, pain, or aseptic loosening around the implant.[38] Persistent immune activation may impair osseointegration and contribute to early implant failure, as described in clinical studies on orthopedic patients, highlighting the diagnostic challenges associated with metal implant allergy, noting that delayed-type hypersensitivity reactions often present with subtle inflammatory symptoms and may lead to soft-tissue complications.[39,40] In addition, research by Granchi *et al*.[41] showed increased immune-mediated reactions in patients with metal-on-metal prostheses, while broader allergology studies indicate that genetic predisposition and chronic exposure significantly influence susceptibility to metal allergy.[42]

Device–tissue interaction

Device–tissue interaction is a fundamental process following implantation and is driven by the foreign body reaction, which involves protein adsorption, macrophage recruitment, chronic inflammation, and fibrous capsule formation.[28,43] Excessive fibrosis can impair device function, such as restricting pacemaker lead mobility, reducing SCS efficacy, or limiting integration of orthopedic implants. Mechanical stress between the implant and surrounding tissues may result in tissue erosion or device migration, particularly in devices that exert chronic pressure

or are inadequately anchored. The material composition and surface properties of implants strongly influence these responses, with advanced biomaterials such as magnesium-based alloys for bone implants enhancing biocompatibility, promoting tissue integration, and minimizing adverse reactions.[44] Understanding these interactions is essential to prevent complications and improve long-term device performance and patient outcomes.

AE reporting systems (Manufacturer and User Facility Device Experience (MAUDE), Medical Device Regulation [MDR], Materiovigilance Programme of India [MvPI])

Post-marketing surveillance systems, such as the Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE) database and the MvPI, track device malfunctions, safety alerts, and recall data. These systems help detect rare or delayed complications not identified during premarket trials.[45-47]

QoL AMONG PATIENTS WITH IMDs

QoL tools and assessment methods (SF-36, EuroQol 5-dimensions (EQ-5D), WHOQOL)

QoL outcomes are critical for evaluating functional recovery, psychological well-being, and patient satisfaction following device implantation. Standardized instruments such as the SF-36, EQ-5D, and WHOQOL assess multiple domains, including physical functioning, emotional health, social participation, and perceived overall health. These tools provide validated measures of PROs, enabling quantitative assessment of the impact of IMDs on daily life, guiding clinical decision-making, and informing comparative effectiveness research. The EQ-5D in particular has evolved as a widely used tool for both clinical and health economic evaluations, reflecting its versatility in assessing health status across diverse populations.[6,7,48]

Cardiovascular implants and QoL

Implantable cardiovascular devices, such as pacemakers and ICDs, significantly improve survival and cardiac function. However, they may also contribute to psychological stress, including anxiety related to potential shocks, concerns about device dependence, and limitations in physical activity.[49] Despite these challenges, most patients report improvements in physical functioning, reduced symptoms, and overall QoL following implantation, highlighting the importance of considering both clinical and PROs when evaluating device effectiveness.[50]

Orthopedic implants and QoL

Joint replacement significantly enhances mobility, pain relief, and social participation, with hip and knee arthroplasty demonstrating some of the highest QoL improvements in orthopedic care. Studies such as Ethgen *et al*.[51] show substantial gains in functional capacity and pain reduction within the 1st post-operative year, while long-term follow-up data from Nilsdotter *et al*.[52] confirm sustained improvements. Recent cohort evidence from Lenguerrand *et al*.[53] demonstrates that although some patients may experience residual stiffness or activity limitations, overall QoL trajectories remain strongly positive across extended follow-up.

Neurological implants and QoL

DBS improves motor function in Parkinson's disease, leading to significant gains in autonomy and daily functioning.[54,55] Some patients may experience mood changes, cognitive effects, or speech disturbances post-implantation. SCS devices effectively reduce chronic pain symptoms, improving sleep, emotional stability, and the ability to perform daily tasks. PROs and validated QoL instruments, such as the Parkinson's disease questionnaire and SF-36, are frequently used to assess improvements in physical, emotional, and social domains following DBS or SCS implantation.[56]

Cochlear implants and QoL

Cochlear implants substantially enhance health-related QoL by improving speech perception, communication ability, and social interaction. Postlingually deaf adults typically experience marked gains in hearing-related functioning and daily activities following implantation.[57] QoL tools such as the Nijmegen Cochlear Implant Questionnaire consistently show improvements in emotional, social, and physical domains after cochlear implantation.[58] Even elderly recipients report significant benefits, including better auditory rehabilitation, reduced tinnitus severity, and decreased stress levels, demonstrating that CI-related QoL improvements extend across age groups.[59]

INFLUENCE OF UNDERLYING PATHOLOGICAL CONDITIONS

Comorbidities and AE risk

Comorbid conditions such as diabetes, chronic kidney disease, and advanced heart failure significantly raise the risk of post-operative complications, device malfunction, and implant-related infections. Poor glycemic control, especially elevated HbA1c or perioperative hyperglycemia, is strongly associated

with a higher incidence of periprosthetic joint infections after hip and knee arthroplasty.[60] Similarly, chronic kidney disease increases mortality and complication rates in patients with cardiovascular implants such as ICDs.[61] These comorbidities negatively influence postoperative recovery and overall QoL, underscoring the need for optimized preoperative evaluation and meticulous perioperative management.[62]

Pathology affecting QoL

Underlying pathology plays a decisive role in shaping QoL outcomes after device implantation. Patients with advanced neurological disorders, particularly Parkinson's disease, often present with significant non-motor symptoms that substantially reduce baseline QoL and may limit postoperative gains, even when motor improvements occur with DBS.[63] Similarly, individuals with moderate-to-severe heart failure frequently experience persistent fatigue, dyspnea, and functional limitations that continue to affect daily life following pacemaker or ICD implantation. Studies show that heart failure patients report markedly lower QoL compared with other chronic diseases and that symptom burden strongly correlates with functional outcomes.[64] Moreover, diverse heart failure populations consistently demonstrate impaired baseline QoL, with only partial recovery despite optimal device therapy.[65] Thus, the severity and nature of the underlying disease significantly modify the extent of QoL improvement achievable through implantable devices.

Role of mental health

Mental health plays a critical role in shaping perceived QoL and the burden of AEs in ICD and pacemaker recipients. Depression and anxiety are common, affecting approximately 20–30% of patients, and can amplify the perception of device shocks, palpitations, or surgical pain.[66] Anxiety and depressive symptoms may also reduce adherence to lifestyle modifications and limit engagement in daily activities. Psychological interventions, including counseling, cognitive-behavioral therapy, structured device-education programs, and support groups, have consistently demonstrated improvements in QoL and reductions in device-related distress.[49,67] Importantly, poor mental health in this population has been linked to higher rates of inappropriate shocks, hospitalizations, and adverse clinical outcomes, highlighting the need for early identification and intervention.[66,67]

Age and gender differences

Age and gender significantly influence AE risk and QoL outcomes. Elderly patients experience higher rates of procedural complications, including infection, lead dislodgment, and post-operative cognitive decline, and tend to recover more slowly after orthopedic and cardiac implants due to frailty and comorbid burden.[68] Younger individuals, conversely, face psychosocial concerns such as body-image issues, device visibility, or activity restrictions, particularly with ICDs and cochlear implants.[69] Gender differences are also evident; women often report higher pain perception and lower QoL after orthopedic implants, whereas men show higher anxiety levels following ICD implantation. Systematic reviews suggest that gender may additionally influence ICD clinical outcomes and the benefit of primary prevention, with men generally deriving a greater survival advantage than women in severe left ventricular dysfunction.[70]

SAFETY MONITORING AND DEVICE VIGILANCE

Regulatory systems (FDA, EU-MDR, central drugs standard control organization [CDSCO])

Global regulatory bodies, including the U.S. FDA, the European Medicines Agency under the EU-MDR, and the CDSCO in India, define standards for device safety, quality testing, and post-approval surveillance. Medical devices are classified based on risk (Class I–III) and undergo premarket evaluation, clinical trials, and periodic safety updates.[71] Post-market surveillance, including recall alerts, AE reporting, and field safety corrective actions, ensures ongoing safety throughout the device lifecycle.[72]

Materiovigilance programmes (MvPI, hospital reporting)

Materiovigilance involves systematic monitoring of device-associated AEs in clinical settings. In India, MvPI mandates hospitals and clinical sites to report device malfunctions, infections, failures, and near-miss events to the regulatory authority CDSCO through designated reporting centers. Pharmacists, biomedical engineers, and clinicians play a critical role in documentation, assessment, and risk mitigation.[73] Materiovigilance helps identify rare complications early and guides regulatory actions, including safety notices and device recalls. National and international reviews highlight that a robust devicevigilance system is essential to ensure long-term safety of implanted and non-IMDs.[74,75]

DISCUSSION

IMDs have become an integral component of long-term disease management by improving survival prospects, functional ability, and overall QoL in individuals living with chronic and disabling conditions. Evidence compiled in this review demonstrates that a wide range of IMDs, including cardiovascular, orthopedic, neurological, sensory, and metabolic implants, contribute to symptom control,

restoration of physical function, and greater independence in daily living.[10-13,14,15,19-21,25,26] Nevertheless, their clinical value must be weighed against the potential for AEs that can compromise long-term outcomes.

Several device-specific complications continue to challenge clinical practice. Mechanical malfunction, premature power failure, lead or structural damage, and material deterioration can lead to repeated surgical interventions, particularly with cardiac rhythm devices and orthopedic prostheses.[1,7,29] Procedural risks, including infection, bleeding, tissue injury, lead displacement, or issues related to anesthesia, also contribute to early morbidity and delayed recovery.[30,31] Among the different AE categories, implant-associated infections remain a major threat to device survival. Opportunistic pathogens such as *S. aureus* and *S. epidermidis* form antibiotic-resistant biofilms on device surfaces, often necessitating complete removal of the implant for successful eradication.[32-37] In addition, hypersensitivity to metals or implant materials can trigger chronic local inflammation, impair osseointegration, and accelerate implant failure, particularly in orthopedic applications.[38-42]

Despite these risks, PROs consistently show that IMDs confer meaningful improvements in physical functioning, psychosocial well-being, communication, pain relief, and social participation.[6,48-58] Orthopedic implants, for instance, continue to demonstrate sustained enhancements in mobility and pain outcomes.[51-53] Likewise, cochlear implants improve emotional adjustment, speech perception, and cognitive engagement among both adults and elderly users.[57-59] Neuromodulation devices such as DBS and SCS also improve autonomy and daily functioning, though some recipients may experience persistent psychological or neurocognitive issues that need ongoing evaluation.[54-56] These observations emphasize that treatment success extends beyond clinical parameters and must capture real-world QOL improvements.

Individual variability has a strong influence on treatment outcomes. Coexisting illnesses – particularly diabetes, renal dysfunction, or advanced cardiovascular disease – heighten susceptibility to infections, hospitalizations, mortality, and poorer functional recovery.[60-62] Disease severity at baseline also affects the degree of QoL restoration achievable, as seen in Parkinson's disease and heart failure patients who often continue to experience debilitating non-motor or cardiopulmonary symptoms even after device therapy.[63-65] Psychological distress is another determinant of outcome; anxiety, fear of shocks, and depressive symptoms in ICD or pacemaker users can magnify symptom burden, diminish device acceptance, and negatively affect clinical prognosis.[49,66-67] Age and gender-related factors further shape recovery patterns, with older adults experiencing more procedural complications and slower rehabilitation, while younger users may have concerns regarding device visibility, physical restrictions, or body image. Gender-linked differences in pain perception and clinical benefit have also been reported.[68-70]

As device implantation becomes more widespread, dependable surveillance systems are crucial for detecting emerging safety issues. Materiovigilance platforms such as MAUDE and MvPI support early identification of rare or delayed complications, thereby strengthening regulatory action and fostering safer device use in routine practice.[45-47,73-75] Technological advancements continue to redefine the landscape of IMDs. Remote monitoring tools enable rapid detection of arrhythmias or device malfunctions, reducing clinic visits and improving long-term follow-up.[76-80] In addition, new generations of biomaterials – including bioresorbable scaffolds and intelligent coatings – aim to reduce chronic inflammation, hypersensitivity, and device-tissue reaction.[81,82] The integration of artificial intelligence (AI) and data analytics may further enhance safety and efficacy by predicting device failures, customizing neuromodulation strategies, and supporting personalized treatment planning.[83,84]

Overall, the collective evidence indicates that IMDs deliver substantial health and QoL benefits when appropriately selected and monitored. A comprehensive, multidisciplinary approach, engaging surgeons, physicians, clinical pharmacists, mental-health professionals, and biomedical engineers, is essential to maximize therapeutic outcomes while minimizing risk. Future investigations into biomaterial innovation, infection prevention, optimal patient selection, and real-time device analytics will continue to drive safer and more effective use of implantable technologies in clinical care.

FUTURE DIRECTIONS

Smart and connected implants

Modern implants increasingly integrate wireless communication, remote monitoring, and real-time data transmission. Bluetooth-enabled pacemakers and cloud-connected ICDs allow clinicians to track arrhythmias, battery life, and device performance remotely, reducing emergency visits and enabling early detection of malfunctions. Remote monitoring has become the standard of care for many cardiac implantable electronic devices (CIEDs), improving follow-up efficiency and patient management.[76,77] As implantable device use expands, such smart and connected systems promise to enhance long-term safety, patient convenience, and timely intervention.

Bioresorbable and advanced biomaterials

Advances in biomaterials now include bioresorbable vascular scaffolds, nanomaterial-coated implants, and next-generation polymer or ceramic coatings designed to improve biocompatibility and reduce chronic inflammation or hypersensitivity. Bioresorbable scaffolds temporarily

support the vessel and then degrade, minimizing long-term complications associated with permanent metal implants.[81] Emerging surfaceengineering approaches, such as antimicrobial or bioactive nanocoatings, along with intelligent biomaterials, offer promising ways to enhance the safety, functionality, and long-term outcomes of implants.[82]

AI and predictive analytics

AI-driven algorithms are increasingly used to detect early signs of device failure, predict arrhythmic events, optimize stimulation patterns in neuromodulation devices (e.g., DBS), and improve outcomes in implantable cardiovascular and neurostimulation devices. Machine learning (ML) applied to intracardiac electrograms can forecast ventricular arrhythmias seconds before onset, enabling pre-emptive interventions[83] and thus potentially reducing sudden cardiac events. Similarly, in neurostimulation, ML helps personalize stimulation parameters, analyze complex neural signals, and predict patient response, improving efficacy and reducing adverse effects.[84] Broad reviews of AI and ML in cardiac electrophysiology and neuromodulation underscore how predictive analytics and adaptive programming hold the promise of individualized, data-driven device management.[83,84]

Better follow-up systems (Telehealth and remote care)

Telemedicine and remote-monitoring systems are transforming post-implant follow-up protocols. Remote device checks, virtual consultations, and automatic home transmission of device data reduce the need for frequent clinic visits, improve early detection of arrhythmias or device malfunctions, enable prompt interventions, and support better long-term monitoring.[78] Multiple studies have reported fewer inappropriate device shocks, shorter time to event detection, fewer scheduled hospital visits, and – in real-world data – improved survival in patients with CIEDs under remote monitoring compared with conventional follow-up.[79,80]

CONCLUSION

IMDs have transformed modern healthcare, providing life-saving therapies and significantly improving functional outcomes and QoL across diverse patient populations. While technological advancements have enhanced device performance, biocompatibility, and longevity, their use is not without risks. Device-related, procedure-related, infection-related, immune, and tissue interaction-related AEs remain important considerations that can impact clinical outcomes and patient well-being. The integration of PROs and standardized quality-of-life assessments alongside traditional clinical monitoring enables a comprehensive evaluation of device effectiveness, highlighting both benefits and potential complications. Furthermore, robust post-marketing surveillance programs, including MAUDE and MvPI, play a critical role in identifying rare or long-term AEs and guiding safer clinical practices. Ultimately, understanding the interplay between device design, patient characteristics, comorbidities, and real-world outcomes is essential for optimizing the safety, efficacy, and overall impact of IMDs on patient health and QoL.

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