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Major Innovations and Trends in the Medical Device Sector

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Review
SUMMARY
Activities related to medical innovation are accelerating and becoming increasingly important due to the demand for better and less invasive therapies, a rapidly aging population in the developed world and a globally larger population able to afford advanced medical care. Medical Innovation is occurring in the fields of pharmacy, diagnostics and therapeutic imaging, surgical products, interventional procedures and devices. Increasing understanding of basic disease processes further opens the opportunities for innovators. Increased knowledge often cause major paradigm shifts in therapeutic methods.
Key words:

1. GENERAL PERSPECTIVES.

"Already Hippocrates" was a major inventor in medical therapeutics in addition to his contributions to ethics and social aspects of medicine. Although human imagination has always invented, rapid innovation in medicine came after fundamental discoveries occurred towards the end of the 19th century with development of anesthesia and antisepsis. In the 20th and 21th century important scientific discoveries resulted in dramatic changes. Some of these developments represented so-called "disruptive technologies", totally changing treatment paradigms.

The impact of such disruptive technology has been dramatically been described:

*Medical technology innovations will **fundamentally transform the health care delivery system**, providing new solutions with medical devices that will challenge existing paradigms and **revolutionize** the way treatments are administered.*

*With the convergence of many **scientific and technology breakthroughs**, the pace of medical invention is **accelerating**, inspiring hope for better clinical outcomes with **less invasive** procedures and **shorter recovery** times, all in lower cost settings. There are powerful forces at work that are driving **rapid fundamental change** in healthcare delivery.*

In the following a few examples will be given to demonstrate major therapeutic shifts caused by scientific discoveries.

Therapy for peptic ulcer disease.

Peptic ulcer disease has been a major cause of disability, complications and death. Treatment was mainly diet and rest until surgeons started resection of the stomach, decreasing acid production by cutting the vagus nerve or its branches. The paradigm shifted again after invention of drugs to suppress the acid production.

Ultimately ulcer was found to be caused by the helicobacter pylori and peptic ulcer could be *cured* by a short course.

Three Nobel Prizes were award-

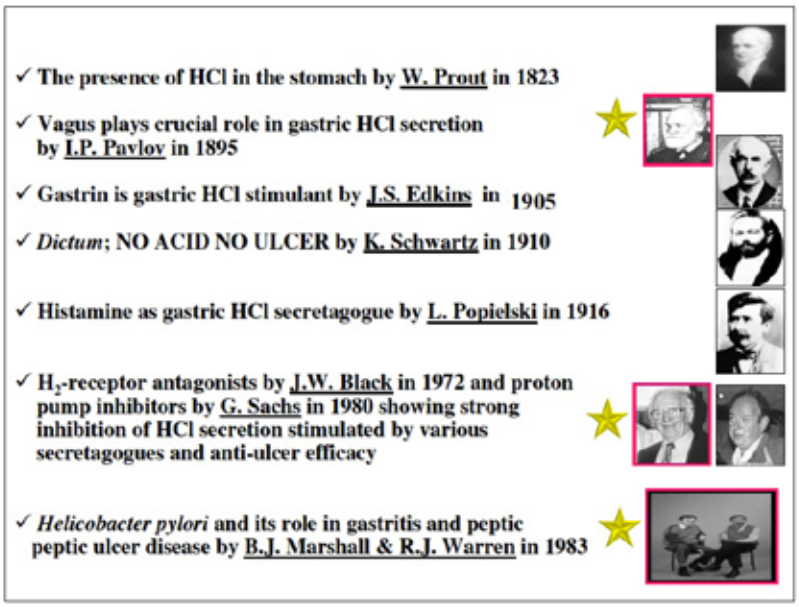

Fig 1. Major contributions to the understanding and therapy for peptic ulcer disease for which Nobel Prize was awarded (Indicated by stars)

ed for work related to peptic ulcer including Pavlov's demonstration of the vagal nerves importance for stimulation of acid secretion (fig1).

According to the prevalent theories about etiology, treatment for peptic ulcer changed from conservative treatment with rest, through surgical treatment and back to a treatment against the offending bacteria, Helicobacter.

2. MEDICAL DEVICES IN CARDIAC DISEASE.

Patients with cardiac disease have benefitted greatly from medical innovation. The cardiopulmonary bypass machine (CPB) made it possible to repair structural heart disease, the pacemaker changed completely the life of patients with cardiac rhythm disturbances.

The development of cardiac pacemakers resulted in some of the most successful medical devices ever produced and formed the basis for a whole industry (1). From relatively simple devices, stimulating the ventricle to treat atrioventricular block, todays pacemaker are advanced digital devices used to treat a variety of cardiac conditions including ventricular fibrillation and heart failure (2, 3).

3. MECHANICAL ASSISTANCE FOR CONGESTIVE HEART FAILURE.

In spite of the excellent results of cardiac transplantation, donor shortage has made transplantation a treatment for few patients with terminal heart failure. Since xenografting (transplantation from different species) is so far a dream that has not come through, mechanical hearts and assist-devices is currently the best option for many patients with terminal heart failure. The cost of devices, relatively common complications and necessary associated medical care is still preventing routine use of such devices (4).

4. REPAIR OF CARDIAC DEFECTS AND CORONARY BYPASS

The invention of cardiopulmonary bypass (CPB) machines was a invention drastically changing the prognosis for helping millions of patients with structural heart disease (5) including coronary bypass operation (CABG) . CABG has been the most common operation performed with CPB. The invention of simple mechanical devices to stabilize regional areas of the myocardium (6, 7), has made CPB optional rather than mandatory for CABG. Availability of flow-metry has made it possible to assure graft patency during the operation, thereby increasing quality and safety of patients undergoing CABG (8). The development of automatic connector devices and minimally invasive surgery using robotics and thoracoscopy has now made it possible to perform CABG through minimally invasive approaches making the procedure more competitive with catheterbased techniques for coronary disease treatment (9-11).

5. PERCUTANOUS CORONARY INTERVENTIONS (PCI)

The description of balloon dilation of coronary arteries by Gruntzig (12), started a revolution in the treatment of coronary artery disease which has continued with the introduction of expandable stents of increasing sophistication. Recently acute PCI in patients with acute myocardial infarction has resulted in further decrease in the already decreasing mortality in this group of patients (13) .

6. TRANSARTERIAL AORTIC VALVE IMPLANTATION.

Treatment of severe calcified aortic valve stenosis was until recently considered an exclusively surgical disease. The surgeons observation of severely calcified valves made it almost unthinkable that catheter-based techniques could replace surgery (Fig2).

Fig 2. Calcified bicuspid aortic valve. Surgical view.

The work of Cribrier (14, 15) starting with balloon valvuloplasty and developing into an aortic prosthesis implantable by catheter technique, shattered this surgical concept. The disruptive TAVI technique is presently reserved for higher risk patients, but this may change rapidly with further sophistication of devices and implantation methods. The most commonly utilized TAVI devices are shown in fig 3 and 4

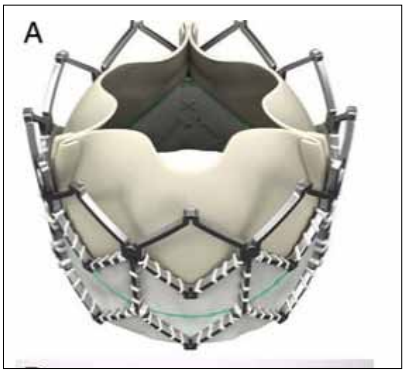

Fig 3 Sapien aortic valve prosthesis. Edwards Inc.

Fig 4. Corevalve aortic valve prosthesis. Medtronic Inc.

7. HYPERTENSION

It is estimated that *one billion* people suffer from hypertension globally. Of these *200 million* are poorly controlled with drugs.

It has been known for decades that denervation of sympathetic nerves may alleviate hypertension,

but the surgery required was too invasive for the treatment to be attractive. Recently, it was demonstrated that radiofrequency ablation of the sympathetic nerves innervating the kidneys, result in significant improvement in patients with resistant hypertension (16, 17).

8. CONCLUSION

In this article we have focused on only a few of the numerous breakthroughs that has transformed the way medicine is practiced. In almost every field and specialty, basic research and innovation has revolutionized the way medical conditions are handled. Many of the new developments have only been available in the developed world, due to economic conditions and lack of access to information in a large part of the world.

The Internet has changed this, making it increasingly difficult for old-fashioned and authoritarian systems to keep information away from people. Telemedicine and teleteaching has given the most remote areas access to the most sophisticated medical knowledge (18, 19). Both in the global society in general and in the medical community the Internet promises instant access to information. This fact will support the goal of widespread access to advanced medical care. Technological breakthroughs combined with mass production and distribution make the wish for improved health and better quality of life,(19) realistic for an increasing part of the global population.

Conflict of interest: none declared.

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