Methodological aspects of deep brain stimulation

Impact

Deep brain stimulation (DBS) is a surgical therapy which has been applied to more than 160,000 patients globally with neurological and psychiatric disorders since the first clinical application and it has been accepted as the standard of care for refractory motor circuit disorders[1]. The annual rate of increase in the number of cases in humanitarian device exempt (HDE) or emerging indications and Food Drug Administration (FDA) approved indications is 36.1% and 7%, respectively[2]. Between 1991-2014, over 7000 scientific papers were published about DBS[3]. The clinical application of DBS therapy stands out as an important area that draws the attention of scientists and it is described as one of the most important developments in the field of clinical neuroscience in the last two decades.

Parkinson's disease and Epilepsy are the indications with the highest prevalence in the general population among the FDA approved indications of DBS therapy[4]. Parkinson's disease is the most common movement disorder disease with a prevalence of 0.3% in the general population and 1% over the age of 60. It is a heavier burden in aging populations[5]. Epilepsy is seen in approximately 50 million patients around the world while 20% of these patients have resistance to anti-epileptic medications[6]. Today, deep brain stimulation therapy is a proven and promising option for patients suffering from these high prevalence neurological disorders[7].

One of the factors affecting the success rate of DBS therapy is the anatomical positioning of the implantable products to the desired structures in the brain with high accuracy. Despite the use of high technology surgical systems and instruments for this purpose, complications linked to several sources are frequently reported in the literature. In a study conducted in the United States between 2004 and 2013, DBS surgeries were investigated from Medicare and Medicaid Services (CMS) and the National Surgical Quality Improvement Program (NSQIP) and the ratio of DBS electrode revision or electrode removal operations to total DBS surgeries was found 15.2% in the first system and 34% in the second system respectively[8]. Moreover, revision cases due to improper targeting or therapeutic efficacy problems were 48% of total electrode revision cases[8]. However, there is no clear data about the reason behind these improper targeted first electrode implantations resulting with lead revision procedures. In addition, there is no study about the financial burden of electrode revision surgeries on health care systems.

DBS electrode revision surgeries can bring time loss and incremental costs to healthcare systems. According to a study in US, an average DBS electrode removal operation and an average re-implantation duration was measured 76.38 min (SD±43.10) and 256.50 min (SD±166.68) respectively[9]. In another study conducted in the US, the average cost of a DBS operation and the average cost of managing complications following the first surgery was reported $40,063 and $4,665.10 respectively[10].

Deep brain stimulation surgeries are mostly performed under two common implantation methods which are asleep and awake surgeries[11]. Awake DBS surgeries are preferred due to the physiological conditions required for microelectrode recording (MER) and macrostimulation applications, while these applications are generally not used in asleep surgeries. However, these applications can bring additional burdens to the centers in terms of time and cost. Moreover, there are opinions that these applications increase the surgical risks of DBS surgeries[12]. However, despite all the time losses and additional costs, the benefits of MER and macrostimulation applications are still supported and advocated by scientists[13].

In this study, we reported the technical complications experienced in our centers that could lead improper surgical planning, misplaced electrode implantations, additional surgical interventions, patient dissatisfactions, time losses and additional costs which could add extra burden to healthcare systems and providers. Following this, we simulated usage patterns that could lead adverse events described above and investigated to what extent these usage patterns affect the accuracy and the output results of surgical planning systems and instruments. Moreover, we discussed the pros and cons of the MER application, which is an important discussion area for DBS literature. We investigated the time-wise effect of MER application for DBS surgeries and shared our perspective on the benefits it provides. Over all, this study will present a different perspective to the DBS literature on management and prevention of adverse events related to technical aspects of DBS surgeries, patient dissatisfactions, loss of time and incremental costs.

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