

Implant MR Imaging Adverse Event Analysis Report "C FDA MAUDE Database Study

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Background

Scanning patients with metal implant under MR systems raises safety concerns. However, many patients with implantable devices have had MR imaging during the past two decades. There continues to be a growing interest within the medical community to allow more patients with implants to have access to MR exams. In order to understand the severity of the risk, we conducted this Post Market Safety study for Implant MR Imaging (Implant MRI).

Materials and Methods

The US FDA MAUDE database was used for this study. MAUDE data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. For this study, the event records for the period from January 1991 to July 2011 were downloaded (1.6GB data). The offline search was performed by finding the events with keywords within Narrative Data (44 keywords) and product code for implantable devices or MR products within Device Data (313 product codes). The narrative search result and product code search results then were linked through matched Events Key within the data sets. To calculate the events rate, the searched product code results were purified by removing the duplicated reports that held the same MDR Key or Event Key. FDA MDR database was also searched. This database contains over 600,000 reports from 1984 – 1996 (365MB data).

Limitations

MAUDE records do not always have sufficient details to explain the cause of the event. Also the number of the records may not reflect the actual events accurately due to the nature of the MAUDE system which allows duplicated reports by manufacturers, facilities, or patients in addition to the potential for under reporting. The purpose of our study is focused on identifying the implant MR imaging reportable adverse events, the calculated event rate is only for reference. As the FDA states on its website: "MAUDE data are not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices".

Results

87 Implant MRI related reportable events were identified from over 3 million records. Out of these 87 cases, 8 patients died; 9 patients faced life-threatening injury such as cardiac arrest, stroke or brain damage; 27 people suffered a burn, pain or a hot sensation and the rest of the 43 patients experienced other consequences caused by implants malfunction or image artifact. **Type of implants:** 19 cases were related to pacemaker/stimulator implants; 7 cases were involved in orthopedic implants; 26 cases were associated with other types of metal implants or metal presence (include aneurysm clips). The remaining 35 cases were related to infusion pump malfunction. Figure 1 illustrates the distribution of the type of implants identified among those 87 cases of Implant MRI reportable adverse events. **Event Rates:** Figure 2 presents the adverse event ratio for various combinations. Implant MRI involved adverse events (MR Implants Event) represents a very small percentage (0.01%) of Total Implants adverse events. Although Implant MRI adverse events represent about 6.6% of the total MR adverse events, the orthopedic implants related adverse events is below 0.64% of the total. The consequences of orthopedic implants adverse events were only in the heating/burn injury category. Figure 2 indicates that the heating/burn injury was the majority of Implant MRI events (about 43%). **Screening**

Information: In the 87 cases identified of Implant MRI events, only 14 cases indicated knowledge of the existence of the implant within patients. However, there was no screening information on the rest of the 73 cases, which are assumed to involve missing or inadequate screening practices. **Events Trends:** Comparing Implant MRI related events with Total Implants events (Figure 3, 4) both events were going up. A possible contributor to the increased event trends might be the increased number of implant procedures and Implant MRI in clinics. Even though the Implant MRI event number increased through the years, its ratio to the Total Implant events dropped significantly from 1992-1995 and stayed below 0.050% thereafter. Similarly, the Implant MRI events and the Total MR events showed a comparable growth trend. The growth might be associated with increased MRI procedures and the Implant MRI might be a contributor to this increasing factor. It was noted that the orthopedic Implant MRI related events did not show a trend of increasing despite the fact that orthopedic Implant MRI increased greatly in recent years.

Conclusion*

There are a variety of reportable adverse events associated with MRI of patients with implants including death, life threatening injuries, heating/burn injuries and device malfunction. The majority of the injuries were involved in active implants such as pacemaker, stimulator or infusion pump implants. The number of injuries slightly increased over the years, but the ratio of Implant MRI injury to Total Implant adverse events or Total MR adverse events have dropped significantly from the early years and stayed low. Furthermore, orthopedic implants were only associated with heating/burn injuries and the number of injuries was about 0.6% compare to total MR related adverse events. Its injury trend was relatively flat which suggests the risk of orthopedic implant MRI was low and well controlled.

* Conclusions are based only on the MAUDE/ MDR data which likely does not represent an accurate or comprehensive sample of adverse events involving MRI.

Reference 1). FDA MAUDE: <http://www.fda.gov/cdrh/maude.html>

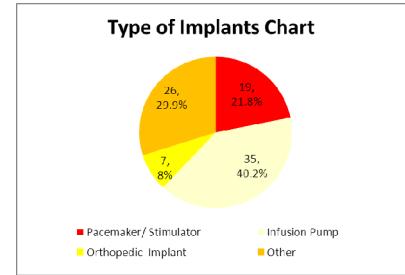


Figure 1 Ratio of Type Implants Involved in MR Events of 1984 -2011 (MDR and MAUDE)

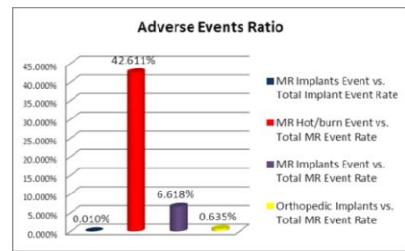


Figure 2 Implants Adverse Events Ratio Calculated from 1991-2011 MAUDE Data

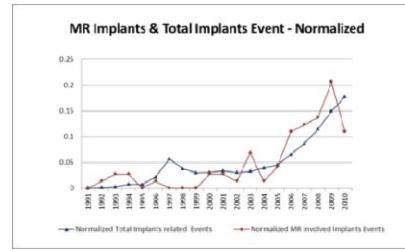


Figure 3 Comparisons of Implant MRI related reportable adverse events with Total Implants reportable adverse events from 1991 to 2010 (MAUDE). 2011 data was removed from the chart since the data were not complete for the whole year. Date was normalized by dividing each year's events number by the total number of the events.

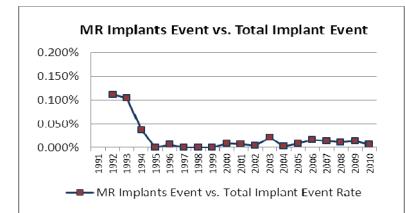


Figure 4 Implants MRI and Total Implants Reportable Events Ratio from 1991 to 2010 (MAUDE)