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Trends in Adverse Events for Ventriculoperitoneal Shunts in the Pre-Pandemic, Pandemic, and Post-Pandemic Eras

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Abstract - A ventriculoperitoneal (VP) shunt is a medical device used to drain excess fluid from the brain to the abdomen. VP shunts aim to treat hydrocephalus, the buildup of fluid in the central and lower parts of the brain. While an effective tool, VP shunts also have limitations and are prone to adverse events. This paper aims to find and analyze trends in VP shunt adverse events in the last decade. The Manufacturer and User Facility Device Experience database was used to search for VP shunt adverse events. The database was searched in yearly increments. While the database relies on reports from patients, caregivers, and manufacturers, the database provides a foundation to observe general trends in adverse events. Generally, injuries were the most common type of adverse event, followed by malfunctions. Deaths were the least common type of adverse event associated with VP shunts. Malfunctions per year fluctuated between 200-600, peaking in 2018 with 564. Injuries per year associated with VP shunts fluctuated between 600-1,200. The most injuries occurred in 2021, with 1,171. The number of deaths associated with VP shunts was dramatically less, with only between 5-30 annually. While the trends are highlighted with this research, further steps can be taken towards the goal of understanding VP shunt adverse events and therefore reducing the amount that occur. Causes of fluctuations, mechanisms behind risk factors, and more patient records can be researched in order to further our understanding of central nervous system shunts. This work is novel because it is the first to assess the rate and severity of adverse events for VP shunts using data from the Manufacturer and User Facility Device Experience database.

***Keywords*:** ventriculoperitoneal shunts, medical devices, adverse events, complications

1. Introduction

The function of a VP shunt is to drain cerebrospinal fluid (CSF) from the brain to the peritoneal cavity in the abdomen. The primary goal of VP shunts is to treat hydrocephalus or the buildup of excess fluids in the brain's ventricles. Hydrocephalus can cause speech, learning, visual, and memory disabilities, and can lead to severe brain damage, herniation, and even death. VP shunts are the most common treatment of hydrocephalus, with an estimated 30,000 shunt implantation procedures performed per year in the United States [1]. VP shunts consist of a ventricular catheter in the ventricles of the brain, that connects to a valve, which connects to a distal catheter, located in the abdomen.

While VP shunts save lives and stop serious problems and disabilities, they also malfunction, leading to injury and death. Some researchers have found that the complication rates of these shunts can vary between 2-20% [2]. However, other researchers find that revision rates in pediatric patients can be as high as 50%, with complication rates in adults ranging between 17-33% per year [3]. Up to 98% of VP shunts fail after a decade [1,4]; , with mortality rates from shunt malfunction ranging from 1-2.7% [5,6]. Research suggests that most complications occur within the first year after shunt implantation, and the likelihood of complications decreases in the second year and again in the fifth year following implantation [7].

On top of the already existing high complication rate for VP shunts, the COVID-19 pandemic introduced additional challenges for healthcare. As healthcare providers struggled to balance public health priorities with care for chronic disease, the result was that necessary surgical procedures were often delayed to limit the spread of communicable diseases. Hospitals suffered from staffing shortages and limited resources. The impact of the COVID-19 pandemic on VP shunt complications has not yet been investigated. The objective of this research is to investigate trends in reported malfunctions, injuries, and deaths for central nervous system shunts in the pre-pandemic, pandemic, and post-pandemic eras.

2. Methods

The Manufacturer and User Facility Device Experience (MAUDE) database is maintained by the U.S. Food and Drug Administration [8,9]. The MAUDE database contains medical device reports of adverse events over the last ten years, updated monthly. The MAUDE database contains medical device reports from both mandatory reporters and voluntary reporters. Mandatory reporters to MAUDE include manufacturers, importers, and device user facilities, while voluntary reporters to MAUDE include consumers, patients, and healthcare professionals.

The MAUDE database was searched using the code JXG, which represents the FDA product code for all devices classified as a "central nervous system fluid shunt and components" within the regulation medical specialty of neurology [10]. The MAUDE database was first searched for JXG malfunctions by year, starting with 2014, and ending with 2023. If a search came back with 500 results, the year was broken up into two six-month segments and added together, as 500 results is the highest amount that the MAUDE database is able to bring back with a single search. A student t-test was used to determine whether changes in adverse events were statistically significant from year to year, with a cutoff for statistical significance of $p<0.05$.

3. Results

The graph of annually reported malfunctions vs. year shows that there was a peak in malfunctions for central nervous system shunts in 2018 (Fig. 1). There was also a high number of reported malfunctions in 2014. The graph reveals significant year-to-year fluctuations in the number of reported malfunctions. For example, there was a statistically significant 38% drop in reported malfunctions between 2014 and 2015, from 498 reported malfunctions in 2014 to 309 reported malfunctions in 2015 ($p<0.04$). There was a statistically significant 53% increase in reported malfunctions from 2017 to 2018, from 368 reported malfunctions in 2017 to 564 reported malfunctions in 2018 ($p<0.005$). There was a statistically significant 30% decrease in reported malfunctions from 2018 to 2019, from 564 reported malfunctions in 2018 to 395 reported malfunctions in 2019 ($p<0.009$). Comparing the years 2018 to 2023, in which the highest and lowest reported malfunctions occurred respectively, there were more than twice as many reported malfunctions in 2018 as there were in 2023, with 564 reported malfunctions in 2018 and 280 reported malfunctions in 2023.

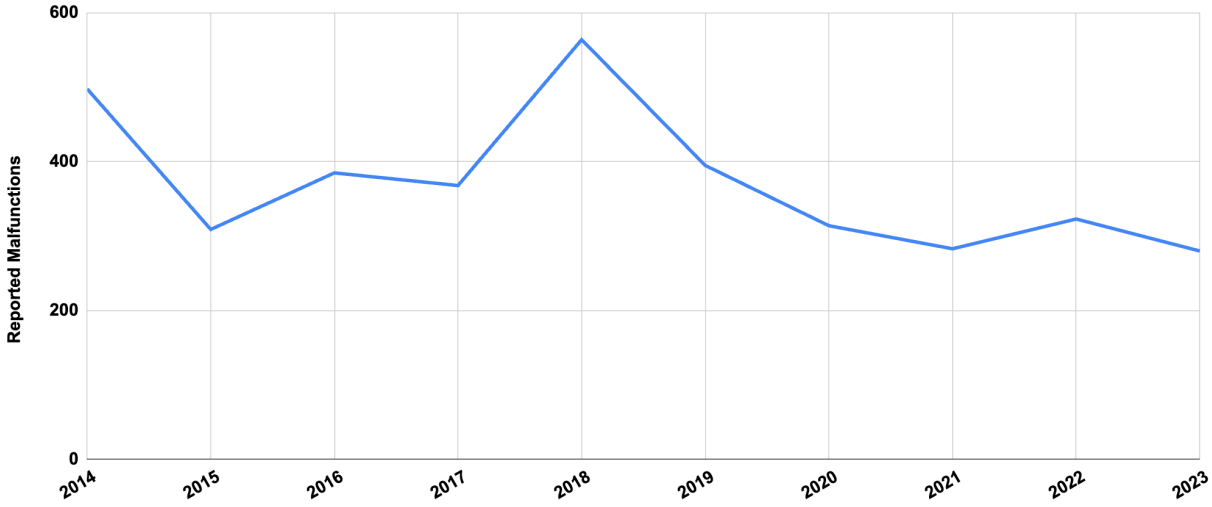

Fig. 1: Reported malfunctions vs. year for central nervous system shunts (FDA product code JXG).

The graph of annual reported injuries vs. year shows that there was a peak in injuries for central nervous system shunts in 2021, with 1,171 reported injuries (Fig. 2). The graph shows many year-to-year fluctuations in the number of reported injuries. For example, there was a statistically significant 37% increase in reported injuries between 2016 and 2017, from 697 reported injuries in 2016 to 956 reported injuries in 2017 ($p<0.03$). There was a 32% increase in reported injuries from 2020 to 2021, from 882 reported injuries in 2020 to 1,171 reported injuries in 2021, but this difference was not statistically significant ($p>0.25$). There was a 15% decrease in reported injuries from 2021 to 2022, from 1,171 reported injuries in 2021 to 994 reported injuries in 2022, but this difference was not statistically significant ($p>0.16$). Comparing the years 2021 to

2015, in which the highest and lowest reported injuries occurred respectively, there were just under twice as many reported injuries in 2021 as there were in 2015, with 1,171 reported injuries in 2021 and 664 reported injuries in 2015.

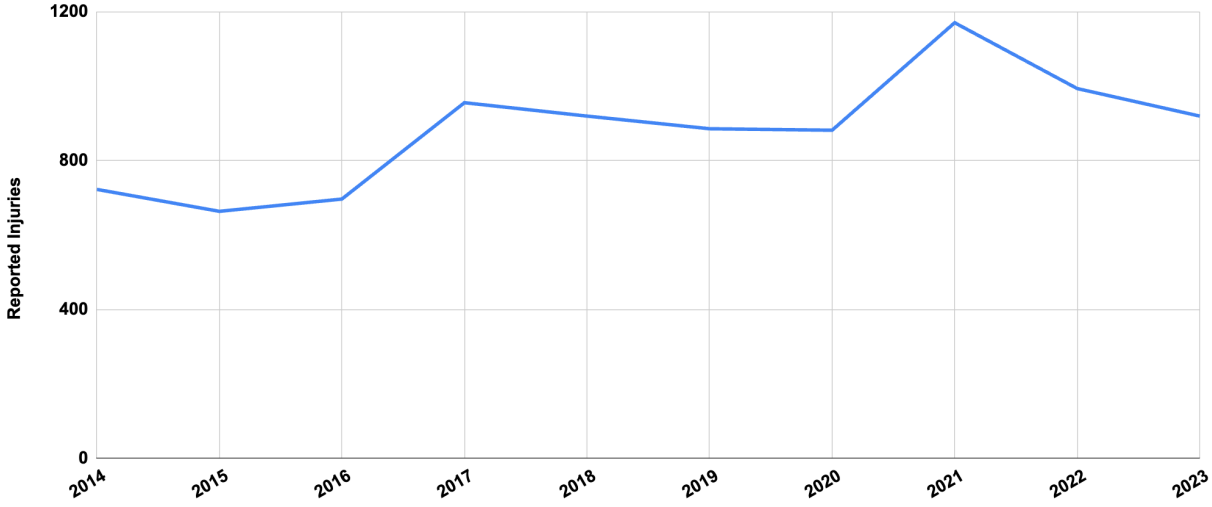

Fig. 2: Reported injuries vs. year for central nervous system shunts (FDA product code JXG).

The graph of annual reported deaths vs. year shows that there was a peak in reported deaths for central nervous system shunts in 2014, with 27 reported deaths (Fig. 3). The graph shows significant year-to-year fluctuations in the number of reported deaths. For instance, there was a 59% drop in reported deaths between 2014 and 2015, from 27 reported deaths to 11 reported deaths, but this difference was not statistically significant ($p>0.10$). There was a statistically significant 200% increase in reported deaths from 2016 to 2017, from 5 reported deaths in 2016 to 15 reported deaths in 2017 ($p<0.02$). Since 2020, the number of deaths has been steadily increasing per year. Comparing the years 2014 to 2016, in which the highest and lowest reported deaths occurred respectively, there were more than 5 times as many reported deaths in 2014 as there were in 2016, with 27 reported deaths in 2014 and 5 reported deaths in 2016.

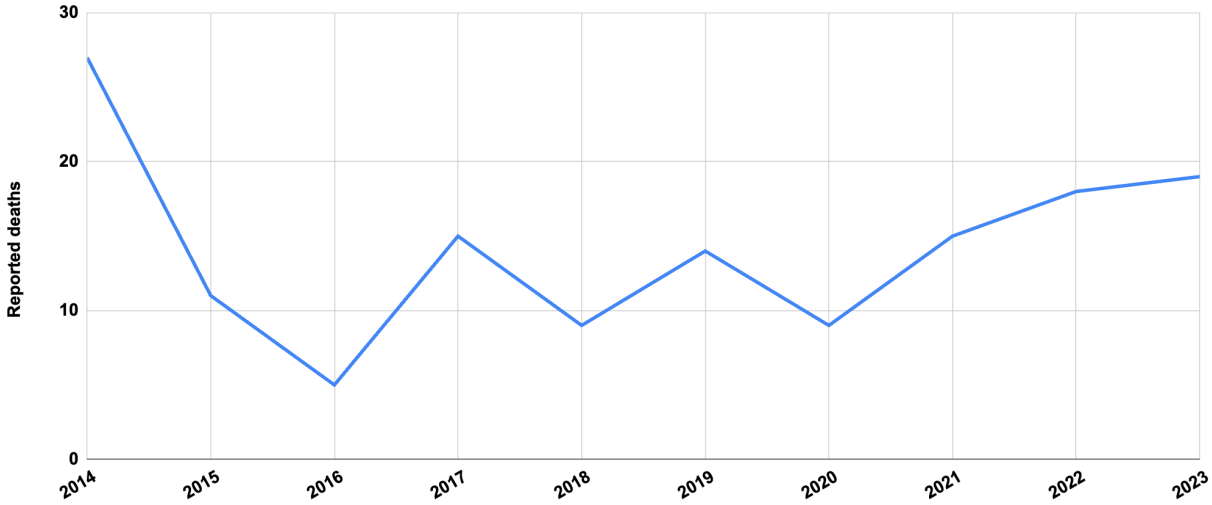

Fig. 3: Reported deaths vs. year for central nervous system shunts (FDA product code JXG).

4. Discussion

While useful to our research, the MAUDE database has many limitations that could impact the accuracy of the data recorded and shown. The MAUDE database relies on reports from manufacturers, patients, doctors, and healthcare

professionals, meaning that false reports or failure to report is a serious issue when assessing the credibility of the data. The FDA cannot observe, confirm, or enforce the submission of accurate reports. Duplicate reports, as well as unreported adverse events, are also concerns. Duplicate reports happen easily when two or more parties involved in an adverse event report it, for instance, the consumer and the healthcare professional. Manufacturers have no incentive to report adverse events, as reports can be time-consuming and demonstrate the failure of their product. In many cases, reports can be downplayed for various reasons, leading to inaccurate reports, and in many cases, adverse event reports are not completely indicative that the product is at fault, as a causal relationship can not be established. Despite these limitations, the MAUDE database remains useful for investigating and surveilling adverse events in a wide variety of devices.

In the data collected from the MAUDE database, the trends in deaths, injuries, and malfunctions for VP shunts seem to have no correlation with one another. The number of deaths fluctuated year-to-year with seemingly no trend, while malfunctions peaked in 2018 and injuries peaked in 2021. This shows that the number of reported malfunctions does not necessarily correspond to injuries or deaths. While this could be a failure to report or a limitation of the database, this could also mean that the circumstances and underlying conditions for malfunctions, injuries, and deaths are not consistent. The number of injuries associated with VP shunt complications peaked in 2021 and remained high in 2022, suggesting a possible correlation between VP shunt complications and the COVID-19 pandemic. In addition, there are multiple risk factors: younger age, history of prematurity, number of revisions, shorter time from insertion to revision, and ethnicity. Blacks, Hispanics, and Native Americans tend to have a higher risk of shunt complication (Bober, Rochlin & Marneni 2016).

Research into VP shunt complications is still limited and multiple areas can be researched further. Most notably, the underlying mechanisms by which some risk factors, such as age and ethnicity, increase complication rates remain unresearched. In addition, fluctuations in complications throughout various time periods can also be researched, as causes are still unknown. A more accurate research method than the MAUDE database could be used, as the MAUDE database has many limitations, as discussed. For instance, a comprehensive survey of patient outcomes following VP shunt implantation would be required to determine the true complication rate. This would enable more accurate data to be gathered, and provide insights into underlying causes, risk factors, and potential correlations, as well as improve patient outcomes.

5. Conclusion

In conclusion, the MAUDE database reveals that the trends in deaths, injuries, and malfunctions for VP shunts do not correlate with one another. The number of deaths fluctuated year-to-year with no apparent trend, while malfunctions peaked in 2018 and injuries peaked in 2021. Therefore, the number of reported malfunctions does not correlate to injuries or deaths. The number of injuries associated with VP shunt complications peaked in 2021 and remained high in 2022, suggesting a possible correlation between VP shunt complications and the COVID-19 pandemic.

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