362

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ASSOCIATION OF ADVERSE EVENT REPORTING WITH DISCONTINUATION OF A SURGICAL DEVICE: THE CASE OF TVT SECUR VERSUS TVT-O FOR TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

Hypothesis / aims of study

Gynecare TVT Secur ™ (Gynecare, Ethicon Inc., Somerville, MA, USA) was the first commercial single-incision mini-sling device available in Europe and North America for the surgical treatment of stress urinary incontinence. The device was first marketed in 2006 and discontinued for commercial reasons in March 2013. We undertook a comprehensive review of the published literature on TVT Secur [1] to explore the events leading to the withdrawal of TVT Secur. At the same time, we became aware that adverse events were being reported on the MAUDE database. The MAUDE system in the USA includes reports of medical device adverse events that are submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers in the USA. The database includes details of individual adverse events and can be searched by brand name. Similar reporting schemes are available in other countries such as Canada, Australia and European countries, but are not as easy to search.

The aims of our current study were to review the MAUDE database to explore the year and type of adverse event reports for TVT Secur compared to TVT-O™ (Gynecare, Ethicon Inc., Somerville, MA, USA), with particular interest in the date of withdrawal of TVT Secur.

Study design, materials and methods

A retrospective review was undertaken of the adverse events appearing in the MAUDE database from 2007 (shortly after the introduction of TVT Secur) to the end of 2014 (21 months after the withdrawal of TVT Secur). Data were collected for each adverse event report for TVT Secur (the device of interest). Data were also collected for TVT-O as a comparison device produced by the same manufacturer during the same time interval. For each adverse event report, the following data were collected: year of report, classification of report (malfunction or injury). The number and type of report for each device was collated by year.

Results

Over the period of interest, there were 1647 adverse events reports for TVT Secure, versus 18 for TVT-O. Only 3 of these reports were for malfunctions (2 for TVT Secur and 1 for TVT-O). In the period before the withdrawal of TVT Secur (pre 2013), there were 18 adverse events reported for TVT Secur, and 14 for TVT-O. The majority (1530/1647, 91%) of the TVT Secur reports appeared in 2013, the year of the device's withdrawal, peaking at 369 reports in August 2013. In the second half of 2014, the rate of adverse event reports for TVT Secur dropped to 3/month.

Interpretation of results

Our study explored adverse events reported for TVT Secur versus TVT-O over the period including the discontinuation of TVT Secur for commercial reasons. Taking into consideration the probable lower volume of TVT Secur devices implanted over the period before 2013 compared to those reported for TVT-O devices, it seems that the actual number of adverse events likely represents a higher incidence rate of adverse events associated with TVT Secur. The huge spike in the number of adverse event reports in the months immediately after TVT Secur was discontinued seems to be associated with reports by attorneys, or instigated by attorneys but reported by others. Our research is seeking further details about the types of individuals reporting adverse events, and about the types of adverse events that are reported.

The main advantage of the MAUDE database is that it can be searched by product name, so it was easy to identify the relevant adverse event reports. However our study also highlights some of the challenges associated with using the MAUDE database for research. A particular problem is the lack of a denominator. We are unable to access the total number of devices either sold or implanted Data are unlikely ever to be made available, even to researchers with no commercial interest in the products, because such information is of great commercial value to the company (in this case Gynecare). We cannot therefore report the risk of adverse events associated with each device. As well, adverse events are often reported years after women have their index surgery, because the event may occur long after the surgery, or else because an adverse event may not be recognised by women as a problem that could be associated with their surgery. In addition, reports may be duplicated if reported on different dates from different sources.

Concluding message

Despite the known problems associated with using the MAUDE database for research, the data provide an interesting insight into the reporting of adverse events. In this case, the comparison between TVT Secur and TVT-O over the short period when TVT Secur was available and the 19 months after its discontinuation, suggests that TVT Secur was indeed associated with more frequent adverse events than TVT-O (given the more widespread use of TVT-O). The spike in reporting of adverse events after TVT Secur's withdrawal, suggests that forces external to the device itself may be causing this increase in reporting. In the past, authors have described the contribution of litigation in regulating devices [2,3]. In this instance, the manufacturer may have made the decision to discontinue TVT Secur in an attempt to avoid litigation.

Clinicians should be encouraged to report adverse events (to MAUDE in the USA or equivalent schemes in other countries) to help to identify unsafe devices, and perhaps prevent patients from being harmed.

Table
MAUDE adverse event (AE) reports for TVT Secur and TVT-O by year

	TVT Secur – reported adverse events n = 1647		**TVT-O – reported adverse events** n = 18	
Year	# of reports	Type of AE	# of reports	Type of AE
2007	1	Malfunction	0	-
2008	3	Injury	1	Injury
2009	3	2xInjury 1xMalfunction	3	Injury
2010	1	Injury	2	Injury
2011	3	Injury	6	Injury
2012	7	Injury	2	Injury
2013*	1530	Injury	1	Injury
2014	99	Injury	3	2xInjury 1xMalfunction

Note: * TVT Secur was discontinued 31 March 2013

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Disclosures

Funding: No funding was received for this research **Clinical Trial:** No **Subjects:** NONE