A Comparison of the Defect Rate Between Original Equipment Manufacturer and Reprocessed Single-Use Bipolar and Ultrasound Diathermy Devices

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Reprocessing has emerged as an attempt to control the cost of single-use bipolar and ultrasound diathermy devices despite limited data on defect rates. This study compares the defect rates, as reported by surgical teams, between original equipment manufacturer (OEM) single-use bipolar and ultrasound diathermy devices and reprocessed (RP) devices. Data were retrospectively collected on 3112 devices over a 7-month period for two types of bipolar and ultrasound diathermy devices. There is a significant difference ($p < 0.001$) in reported bipolar and ultrasound diathermy device defects between OEM and RP. OEM single-use bipolar and ultrasound diathermy devices were reported to be defective more frequently than RP devices based on reports from the surgical team. [DOI: 10.1115/1.4030858]

Introduction

Reprocessing has emerged as an attempt to control the cost of single-use bipolar and ultrasound diathermy devices. Data on the defect rates of these medical devices remain limited [1]. OEMs claim lower defect rates compared to RP devices; however, the Food and Drug Administration (FDA) has reported that RP single-use devices do not present an elevated health risk [2]. It has been noted that errors in processing can lead to increased cost and may result in worse patient outcomes [3]. In addition to patient safety issues, reprocessing can also have legal implications [4].

Understanding the defect rates of these devices as reported by the surgical teams, working under real world conditions, will help clarify the true risk for each type of bipolar and ultrasound diathermy device. The purpose of this study is to compare the reported defect rates between the OEM single-use bipolar and ultrasound diathermy devices to RP energy devices in a single, large healthcare system.

Materials and Methods

This is a retrospective study of data collected over a 7-month period (Jan. 1, 2013–July 31, 2013) for two types of bipolar and ultrasound diathermy devices used, for vessel sealing and dividing, in both open and laparoscopic surgical procedures. One of the OEMs produces ultrasonic (US) diathermy single-use devices. The other OEM produces bipolar diathermy (BD) single-use devices. A total of 680 OEM (US) devices and 713 OEM (BD) devices were used in the comparison along with 1036 RP (US) devices and 683 RP (BD) devices. Any device that was reported as defective by the surgeon, scrub tech, first assistant, or circulating nurse at any time during the course of an operation on a patient was counted as a defect and reported to supply chain services for tracking purposes. The number of devices purchased during this time period was also tracked by supply chain services through purchase orders. This count was used to determine the overall defect rate during the study period. Rates were calculated based on the reported defective devices divided by the number of devices purchased during the reporting period. Comparisons were made between OEM and RP for all bipolar and ultrasound diathermy devices and broken out based on manufacturer type. Devices to be RP were collected from the operating rooms of 19 acute care facilities across seven states and RP through an external vendor who has FDA 510(k) approval to reprocess the single-use bipolar and ultrasound diathermy devices included in this study. RP devices were, therefore, the same model as the OEM device, which the FDA 510(k) approval was based.

This study was determined to be exempt by the healthcare system's Institutional Review Board (Project No. 01-14-0069, Reference No. 014742). Patient data were not used. Only the reported defect rates of the bipolar and ultrasound diathermy devices used during the study period were tracked. Statistical analyses were performed using a two-tailed Z-test for two population proportions. A p value < 0.05 was considered statistically significant.

Results

A total of 3112 devices were purchased and included in the reporting period (OEM: 1393 and RP: 1719). There is a significant difference ($p < 0.001$) in reported bipolar and ultrasound diathermy device defects between OEM and RP, with a higher percentage of defects (2.0% versus 0.41%) reported with the OEM devices (see Table 1). OEM devices were reported as defective 4.9 times more frequently than RP devices. This difference was maintained for both types of bipolar and ultrasound diathermy devices studied, US (OEM versus RP: $p = 0.0013$) and BD (OEM versus RP: $p = 0.009$).

When comparing the OEM US to the OEM BD device, there was no significant difference in the reported defect rates ($p = 0.522$) (see Table 2). This held true for RP devices as well. There was no significant difference in the defect rates between the RP US and the RP BD devices ($p = 0.3472$).

Discussion

In this study, the reported defect rates were compared between OEM and RP single-use bipolar and ultrasound diathermy devices. Over a 7-month period in our healthcare system, it was found that, contrary to popular opinion [5], OEM bipolar and ultrasound diathermy devices were reported as defective more frequently than comparable devices that underwent reprocessing. Previously, Weld et al. [6] demonstrated better performance for an OEM ultrasound diathermy device compared to a RP device based on visual inspection of the device, mechanical testing, and in vivo testing in an animal model. Our study focused on surgical team reporting during operative cases involving patients under real world conditions. It may be that the difference in outcomes may have more to do with how performance is defined.

Table 1 Comparison of OEM versus RP devices

All devices	Defects	Purchases	Defect rate (%)	Z-score	p-value
OEM	28	1393	2.01	—	—
RP	7	1719	0.41	—	—
OEM versus RP	—	—	—	4.216	<0.001
US	—	—	—	—	—
US OEM	12	680	1.76	—	—
US RP	3	1036	0.29	—	—
OEM versus RP	—	—	—	3.211	0.0013
BD	—	—	—	—	—
BD OEM	16	713	2.24	—	—
BD RP	4	683	0.59	—	—
OEM versus RP	—	—	—	2.607	0.009

Manuscript received July 16, 2014; final manuscript received June 8, 2015; published online August 6, 2015. Assoc. Editor: Rosaire Mongrain.

Table 2 Comparison of device based on manufacturer

OEM	Defects	Purchases	Defect rate (%)	*Z*-score	*p*-value
US OEM	12	680	1.76	—	—
BD OEM	16	713	2.24	—	—
US OEM versus BD OEM	—	—	—	−0.637	0.5222
RP	—	—	—	—	—
US RP	3	1036	0.29	—	—
BD RP	4	683	0.59	—	—
US RP versus BD RP	—	—	—	−0.943	0.3472

For the purposes of this study, "defective" was defined as any time a member of the surgical team (surgeon, scrub tech, first assistant, or circulating nurse) determined that the bipolar and ultrasound diathermy device was not functioning in a manner consistent with the devices intended purpose. Most commonly, this was either the surgeon or scrub tech that made this determination. When it comes to the OEM and RP manufacturers, testing is performed under laboratory conditions, whereas this study was designed to evaluate these devices under real world operating conditions with the people who work first-hand with the equipment. This is, no doubt, a much more rigorous condition which explains the relatively higher defect rate. What is not apparent is why OEM devices were reported as defective more frequently than RP devices.

The U.S. FDA's Code of Federal Regulations (CFR) states "each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria" [7]. The FDA allows for medical device testing to be performed by sampling as long as the manufacturer uses valid statistical techniques. Sampling allows a manufacturer to ensure a predictable level of confidence that the defect rate is acceptable [8]. A defect rate can be seen as being derived from in vitro testing whereas, in this study, the defect rate is derived from in vivo testing. Furthermore, when an OEM device is reported to be defective it is removed from the potential supply source for a RP device. Only those OEM devices that passed in vivo testing in the operating room are deemed suitable for reprocessing. In addition, the reprocessing manufacturer in this study does not use a sampling method for testing. All of their RP devices are tested before being distributed for use in the operating room. RP devices should have a lower defect rate since OEM devices reported as defective are removed from the RP supply chain and each is tested prior to distribution.

Limitations of this study include lack of confirmation data on why devices were reported as defective. It is unknown exactly, why each device was reported to be defective by the surgical team. Confirming this information could change the number of devices reported as defective. For example, if a device was reported to be defective and the issue was really operator error, then this would erroneously classify the device as defective. Similarly, a device in which sterility was compromised by one of the operators prior to use could be reported as defective when, in fact, the device would have functioned as intended. Lacking true causation for the device being reported as defective limits our understanding of the differences noted in the results. The difference between types of defects, such as mechanical (faulty circuit), operational (device's sterility compromised), or system (education on proper use of device), is critical for correcting the issue responsible for the defect. Unfortunately, a breakdown of the type and cause of the reported defect was not available for this analysis. A more robust data collection process is essential for this type of process improvement.

An additional limitation is that it is possible that a device reported as defective was purchased before the reporting period and left unused for more time, or a purchased device, counted in the denominator, was reported as defective after the reporting period. While inventory is screened for expiration dates, it may be that OEM devices remained on the shelf longer before being used and are at risk for device malfunction compared to RP devices which may have a more rapid turnover in our system. Without the ability to track individual devices in our system, this possibility cannot be excluded. Another limitation of this study is that patient outcomes were not included in the analysis. Since bipolar and ultrasound diathermy devices that are reported to be defective are replaced with devices that are used successfully, patient care may not be impacted, regardless of whether an OEM or RP device is used. Unfortunately, encounter level detail on clinical outcomes was not available for this analysis. Having a mechanism to track a device throughout its life-cycle may assist in this endeavor.

Recently, the FDA approved the final rule for implementing the unique device identification (UDI) system for medical devices in 2013 [9]. UDI was designed to identify a device from distribution to use. A UDI could allow for more accurate reporting of defects, tracking of specific reasons for the defect, comparing like models, and correlating this information with patient outcomes. In addition, knowing if a device passed a sampling test but became defective during the course of an operation would assist manufacturers in producing devices with greater real world reliability and value. In the era of value-based purchasing, medical devices that cost twice as much [10] and are reported to be defective more frequently challenge conventional definitions of reliability and value.

Conclusions

OEM single-use bipolar and ultrasound diathermy devices were found to be defective 4.9 times more frequently than RP devices based on surgical team reporting. The overall defect rate for OEM bipolar and ultrasound diathermy devices was 2.0% and was not significantly different based on manufacturer.

Acknowledgment

The author wishes to acknowledge the support of the Division of Care Management and Supply Chain Services of Banner Health in the development of this manuscript.

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