Green in the O.R.

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Introduction

United States health care spending in 2015 was $3.2 trillion dollars, or 17.8% of the GDP. (1) It is predicted that, without intervention, this will reach 20% by 2025. It has been recently calculated that the healthcare industry in the United States accounts for nearly 10% of the country's carbon dioxide emissions. (2) Beginning in the year 2000, a novel approach to curtail both of these rising trends was introduced. This was the reprocessing of Single Use Devices (SUD). The idea behind this was that many devices used in the healthcare arena that were intended for only a single patient use, from blood pressure cuffs and laparoscopic trocars, to cardiac catheterization balloons could be used beyond a single patient. In doing this, costs can be cut, as well as the environmental impact of the industry as a whole. This can only be accomplished if certain safeguards are in place to ensure that these Reprocessed Single Use Devices (RSUD) are properly cleaned, re-sterilized if necessary, and thoroughly checked to make sure there are no defects in the products from past use. The sale of these RSUDs can be done at a lower price than the original device, which can save in healthcare dollars. And as stated before, the environmental impact can be lowered as new devices are not created from scratch.

The RSUD industry has been growing over the last 17 years. In the United States, 90% of the reprocessing of medical devices is performed by four main companies: Sterile Med (Johnson and Johnson), Nellcor (Medtronic), Ascent (Stryker), and ReNewal Reprocessing (Medline) (2). Industry

representatives state that this is currently a 400 million dollar a year industry. They also project a 14% growth rate per year with a final industry potential of 2 billion dollars per year. As the size of this industry increases, two things will most likely happen. With the savings available to hospitals using RSUDs, these instruments will become more prevalent in our clinical settings. Along with this will come closer scrutiny of quality metrics when these devices are used, such as infections and outcomes.

The federal government regulated RSUDs through two pieces of legislation. The first policy, passed in August of 2000 makes the third party that is reprocessing the RSUD legally the manufacturer of the reprocessed device, and liable for any failure of the device. Because of this, many hospitals that were reprocessing devices themselves turned to third party purveyors to handle this for them. It also set reprocessing standards, but oversight was inconsistent with this policy. The second piece of legislation was the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This act required the labeling of all reprocessed devices as such, and also required the identity of the reprocessor be on the device. At the same time the FDA increased their oversight of the industry, requiring published results of re-sterilization, effective cleaning and functional performance before an instrument could be released (3). The reprocessing companies must also track device failures, and recall any devices that are deemed unsafe.

RSUDs come in many shapes and sizes. These devices include blood pressure cuffs, pneumatic compression sleeves, cardiac catheterization balloons, and laparoscopic instruments. We will concentrate on the RSUDs that fall into this last category. The life cycle of an RSUD begins with the hospital agreeing to dispose of single use instruments that meet the criteria for reprocessing with the third party company. These devices go in separate bins and are removed from the hospital by the reprocessing company. It should be noted, this alone is a money saving proposition for the hospital, as they do not have to spend money on the disposal of medical waste for these devices. The device then is

taken for cleaning and sterilization at the third party's reprocessing center. The cleaning is either done by hand or by machines, with or without enzymatic agents. Once cleaning has been completed, refurbishing and repair of the devices takes place. Sterilization can then be completed, and the product is ready to be shipped.

As stated before, there are two ways that hospitals save money when partaking in a reprocessing program. The first way is on the front end by having their medical waste removed free of charge by a third party. The second way is in cost savings in using reprocessed instruments which are significantly less expensive than the same products from the original vendor. One reprocessing company that holds approximately 60% of the market share claims they saved their participating health care customers $299 million in 2016 alone. If extrapolated to the entire industry, this would mean a savings of half a billion dollars. They would not disclose how many hospitals took part in 2016. The secondary savings this industry provides is to the environment. There is a benefit to using things more than once, with a decrease in the environmental impact of the healthcare industry as a whole. The same company states that they diverted 12.9 million pounds of waste from landfills over 2016. Again, extrapolated to the whole industry, this is 21.5 million pounds of waste saved. While we must rely on industry for the numbers when it comes to waste diversion, this benefit cannot be discounted.

Outcomes and Performance of RSUD

Examination of available studies on outcomes and performance of RSUDs show some differences in performance based upon in Vivo and ex Vivo testing, as well as surgeon preference. However, there is little data that supports obvious clinical detriment in patient outcome. Still, serious ethical concerns exist based in fear of unknown infectious, mechanical, and other potentially harmful side effects from the use of reprocessed laparoscopic instruments designed as single-use only by the original manufacturer (Hailey). Performance differences in remanufactured or reprocessed and first time single-

use instruments seem to vary based upon the type of instrument in question. We will focus on three types of RSUDs in this report: laparoscopic insufflation ports, laparoscopic graspers, scissors and hook cautery, and ultrasonic vessel sealing devices.

Current literature evaluates outcomes of RSUDs in one of two ways, infectious transmission and mechanical function. Infectious transmission is defined as the ability of reprocessed instruments to be reliably and completely sterilized by accepted sterilization techniques. Mechanical function of the reprocessed device encompasses everything that makes the device do what it is intended to do. This may include the opening and closing of the device jaws, the force needed for insertion of the device, effective actuation of the desired tissue effect, failure of the device with the possible need for intraoperative replacement, and finally prevention of any undesired tissue manipulation that may result in patient harm.

Laparoscopic insufflation trocars

Most surgeons and institutions in the United States currently use disposable laparoscopic insufflation trocars despite multiple studies indicating the cost efficiency of reusable metal trocars. Equipment manufacturing companies are financially incentivized to produce single-use instruments and this provides supply-side drive for the use of disposable trocars. Financially, demand-side drive for disposable trocars can be seen in the reduction in hospital upfront equipment costs, personnel time and skill for disinfecting, and equipment repair costs. From a patient and surgeon use / safety point of view, there are several advantages of plastic non-conductive and optical entry clear tip design trocars in both reducing unintended electrosurgical energy via capacitive coupling and for optical peritoneal access techniques. These forces, whether safety, ease of use, or financially driven have combined to produce millions of plastic component disposable trocars produced and consumed by US hospitals and surgeons. This provides the obvious opportunity for reuse with potential cost and environmental impact savings.

Challenges pertaining to the reuse of single use laparoscopic insufflation trocars are mainly that of infectious transmission with a lesser but not insignificant concern for performance of the valve and ease of trocar insertion . The complex nature of the port and valve design can theoretically lead to ineffective sterilization In several studies using in vitro testing techniques (4,7,19). Other in vivo studies have shown no increase risk in infectious risk or complications with the use of reusable single-use trocars. Dos Santos evaluated 28 reusable trocars from multiple manufacturers after laparoscopic cholecystectomy and found the presence of bacteria and fungi on 46% of these trocars. After recommended sterilization techniques, 0 of the 28 trocars had microorganisms detectable in cultures (Santos).

Surgeons often experience laparoscopic trocar valves contaminated with solid and liquid debris which smudges the endoscope lens during insertion, causing poor visualization. This valve contamination necessitates more frequent endoscope cleaning and likely extends operative time, increases surgeon frustration and potential for errors (6). Many surgeons feel RSUD trocars have damaged valves that lead to worse port valve contamination although little published data exists regarding valve contamination and its impact on procedures. Multiple port and lens cleaning devices have been developed to facilitate lens cleaning and one study showed significantly shorter lens cleaning time with a completely endoscopic device that cleans from the inside thereby eliminating repeat lens contamination by a contaminated valve (6).

Ease of trocar insertion has been studied comparing reusable and single use as well as reused single-use trocars and favors reusable and first-time use disposable instruments over reprocessed trocars (13,16). This force insertion approach to analyzing ease of trocar insertion theorizes that less force equates to less risk of internal visceral or vascular injury especially with initial trocar insertion. We should note however that with different port insertion techniques of open, Veress needle, and direct

optical entry combined with variable surgeon experience and patient characteristics, port insertion force alone may be less important in determining the safety of the trocar. The blade “sharpness” seems less important for bladeless direct optical entry trocars than optical clarity which does not seem to diminish significantly with reprocessing of these single use trocars although there is no published data.

Laparoscopic graspers, scissors, hook cautery

This group of laparoscopic instruments are much more commonly reusable in the United States however single-use and therefore RSUD graspers, scissors, and cautery are used and can have some technical advantages as well as patient safety advantages. RSUD graspers may have special tip designs allowing a cushioned grasping of more sensitive visceral organs such as bowel. No studies could be found on mechanical failure and reuse or safety issues with RSUD graspers compared to first-time devices, however mechanical failure must lead to eventual disposal of these reprocessed graspers. RSUD scissors may potentially have sharper blades and function better than reusable scissors if the facility does not maintain their reusable instruments optimally. No data exists to confirm this however. Colak et al. compared first use disposable instruments with reprocess disposable instruments for laparoscopic cholecystectomy total complications and infection rates and found no significant differences in 125 patients (8).

Capacitive coupling was considered a main source of laparoscopic electrosurgical injury with early use of metal trocars. Plastic trocars commonly used in the US today have reduced this risk and currently instrument insulation failure is considered the highest cause of laparoscopic instrument electrosurgical injury. In 2010, Montero found that 1 in 5 reusable laparoscopic instruments had insulation failure and this was not improved in hospitals that regularly check for insulation failure. Disposable instruments had a 3% incidence of insulation failure compared to 19% for reusable instruments in this study (Montero). Unfortunately this better insulation advantage of disposable electrosurgical laparoscopic instruments

should be expected to fade with increasing use of the RSUD. One study confirms this specifically for DaVinci robotic instrumentation showing a high prevalence and incidence of insulation failure after 10 uses of DaVinci limited use disposable instrumentation compared with laparoscopic instrumentation. 81% of the robotic instruments had insulation failure compared to 19% of the laparoscopic instruments (10). These shocking statistics do not include the potential effect of capacitive coupling combined with DaVinci robotic procedures that utilize reusable metal trocars. Many advocate improved testing with high voltage detectors for all instruments used for electrosurgery given the high incidence of insulation failure (18). SAGES FUSE educational program was developed to better educate surgeons regarding the risks of electrosurgery and advocates lower voltage electrosurgery and alternative surgical energy sources to improve patient safety (FUSE).

Ultrasonic harmonic scalpel

The ultrasonic harmonic scalpel (HS) (Ethicon) uses ultrasonic energy to generate heat and achieve tissue dissection and vessel sealing as well as providing an instrument for grasping and tissue manipulation. Reprocessed or more accurately termed, remanufactured harmonic scalpel devices, that are processed according to FDA regulations were determined by the FDA in 2006 to be as safe and effective as new ones. Given the higher initial expense of HS there is significant cost savings possible with the reuse of these devices and one study estimates this savings as $194 USD per case (11,21).

Safety and performance of these more complex RSUD laparoscopic devices has been thoroughly studied by both the original manufacturer and companies that remanufacture the HS. While one study shows significantly greater performance of new HS compared to remanufactured HS, several other studies show equivalence and equal function (5,11,14,21,20). More recent Internal testing by Ethicon shows a higher burst pressure and better temperature control for their HARMONIC ACE + 7 HS than Stryker

Sustainability Solutions HAR36 reprocessed devices (Ethicon energy updates). No studies are published whether this translates into better clinical outcomes or improved patient safety.

Conclusions

There is a scarcity of data reviewing the outcomes of RSUD use in the clinic field. While there are some studies, many sponsored by the company that makes the original product, that show insufficient cleaning and decrease effectiveness of the reprocessed instruments, there has not been a study to show that this translates to the clinical field, or has a deleterious impact on patients. The data for cost savings and decrease in medical waste cannot be ignored. There is a real dollar amount saved in using reprocessed instruments. There is also a real environmental impact in using instruments more than once. This industry is projected to grow over the next decade to nearly double its current size. While there is no data to suggest that there are worsened patient outcomes using RSUDs, research in this area would help elucidate this issue. However, with the increased scrutiny of the cost of health care by multiple entities, and the clear positive impact these products have on the environment, their use will continue to grow in the foreseeable future.

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