ORIGINAL RESEARCH

# Medtronic I-Drive vs Ethicon Echelon: A Head-to-head Randomized Controlled Trial

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## Abstract

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**Background:** There have been numerous studies comparing various aspects of bariatric surgery, such as hand sewn vs stapled anastomoses, electronic vs manual staplers, and reinforced vs nonreinforced staple lines. There has never been a randomized controlled trial comparing different staplers in sleeve gastrectomies.

**Methods:** Our study was a randomized control trial comparing the staple reload time, complications, and stapler cost for the Medtronic I-Drive and the Ethicon Echelon. Our primary endpoints were time, hemostasis, bleeding, necessity for transfusion, and leak rate in a military system.

**Results:** Sixty-three patients were consented for the study with a final number of 26 in the Echelon arm and 25 in the I-Drive arm after fallout. There were a total of 140 stapler reloads in the Echelon arm and 123 in the I-Drive arm. The median staple reload times were 39.78 seconds for the I-Drive and 41.77 seconds for the Echelon ($p = 0.42$). The total time for sleeve creation was 12.14 minutes in the Echelon arm and 14.26 minutes in the I-Drive arm ($p = 0.04$). There were two misfires in each group (four total) and no positive leak tests, transfusions, or postoperative complications. The average cost for staplers, reloads, and reinforcement for the I-Drive was $2,037.26 for the civilian rate and $2,097.66 for the government rate. The average cost for the Echelon was $1,835.65 for the civilian rate and $2,268.97 for the government rate.

**Conclusion:** The Medtronic I-Drive and the Ethicon Echelon are comparable in reload time, stapler misfires, leak test rates, and cost.

**WBAMC IRB Study Trial Number:** NCT02731079.

**Keywords:** Bariatric surgery, Linear stapler, Minimally invasive surgery.

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## Introduction

Obesity rates in the United States continue to rise and with the CDC reporting the prevalence rate of obesity in adults at 42.4% as of 2018.[1] The rate of bariatric surgeries in the United States has risen in a concomitant fashion. The total number almost doubled between 2011 and 2018 with 252,000 bariatric surgeries performed in 2018 and sleeve gastrectomies representing the predominant growth at 61.4% of bariatric interventions.[2]

In the late 1980s, Dr Doug Hess developed the sleeve gastrectomy as an alternative to the vertical gastrectomy, which imparted a restrictive function to the biliopancreatic diversion.[3–5] Addition of a gastrectomy to the biliopancreatic diversion also allowed for a reduction in the length of bowel bypassed without compromising weight loss results and preservation of the pylorus aids in decreasing complications like dumping.[6–8] In the early 2000s, sleeve gastrectomies developed into a shorter, safer initial operation for the super morbidly obese population in preparation for a more extensive operation, such as the Roux-en-Y gastric bypass or the biliopancreatic diversion.[9] However, in recent years, sleeve gastrectomies have established their role as a safe, single-stage operation.[10]

The most significant early postoperative complication is bleeding from the long staple line with reported rates as high as 16% with an average of 3.6%.[11–13] Another serious complication is the development of a gastric leak with reported incidences as high as 3.7%, which are more commonly found at the proximal anastomosis compared to the distal.[14–16] Various proposed modalities for decreasing the rates of these complications include oversewing the staple line, buttressing the staple line with organic or synthetic reinforcement material, and placing biological sealant.[17] There is a general consensus that any staple line reinforcement is superior in preventing leaks compared to no reinforcement, but evidence for a superior type of reinforcement remains controversial.[18–20]

With a rising popularity in sleeve gastrectomies among bariatric surgeons and patients, comprehensively researching all aspects of the operation is critical for optimizing patient outcomes. There have been many studies evaluating the safety and efficacy of sleeve gastrectomies, but to our knowledge, there is a paucity of data available for head-to-head analyzes of the time and cost differential between competing linear stapler devices with an absorbable polymer membrane reinforcement. We sought to compare the Ethicon Echelon Flex with Seamguard bioabsorbable reinforcement (W.L. Gore & Associates, Inc.) with the Covidien Endo GIA reinforced reload with tri-staple technology (Medtronic, Minneapolis, Minnesota, USA).

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**Conflict of interest:** None

## Methods

We designed a randomized control trial that received institutional IRB approval. All patients underwent surgery at our facility after completing our institutional bariatric pathway to include bariatric seminars, support groups, extensive medical workup, and psychological evaluation. We excluded patients from participating in the study if they needed revisional surgery or presented with inflammatory bowel disease. We counseled all patients that each of the linear staplers used in the study are approved devices for their surgery and the surgeons performing the operation trained to operate with both devices. A total of 63 patients consented to participate in the study and randomized to each arm.

The Ethicon Echelon powered stapler—with and without Seamguard—and the Medtronic I-Drive powered stapler with reinforcement comprised the two arms of the study. All laparoscopic sleeve gastrectomies were performed with an absorbable polymer membrane staple line reinforcement. The majority of surgeons in this study elected to use Seamguard on all Echelon loads except for the load most proximal to the gastroesophageal junction. There were 7 staff surgeons and 19 residents that participated in the study. Patients were randomized into each arm at the time of their consent to the study. Two researchers performed the randomization sequence by annotating the study arm on a sheet of paper along with an arbitrary sequential numerical identifier, which were stored in a secure envelope and blindly drawn at the time of consent. We enrolled all patients that consented within the study period, and an interim analysis demonstrated a prohibitive number of participants would be necessary to demonstrate statistically significant data—at which point study recruitment was concluded (Flowchart 1).

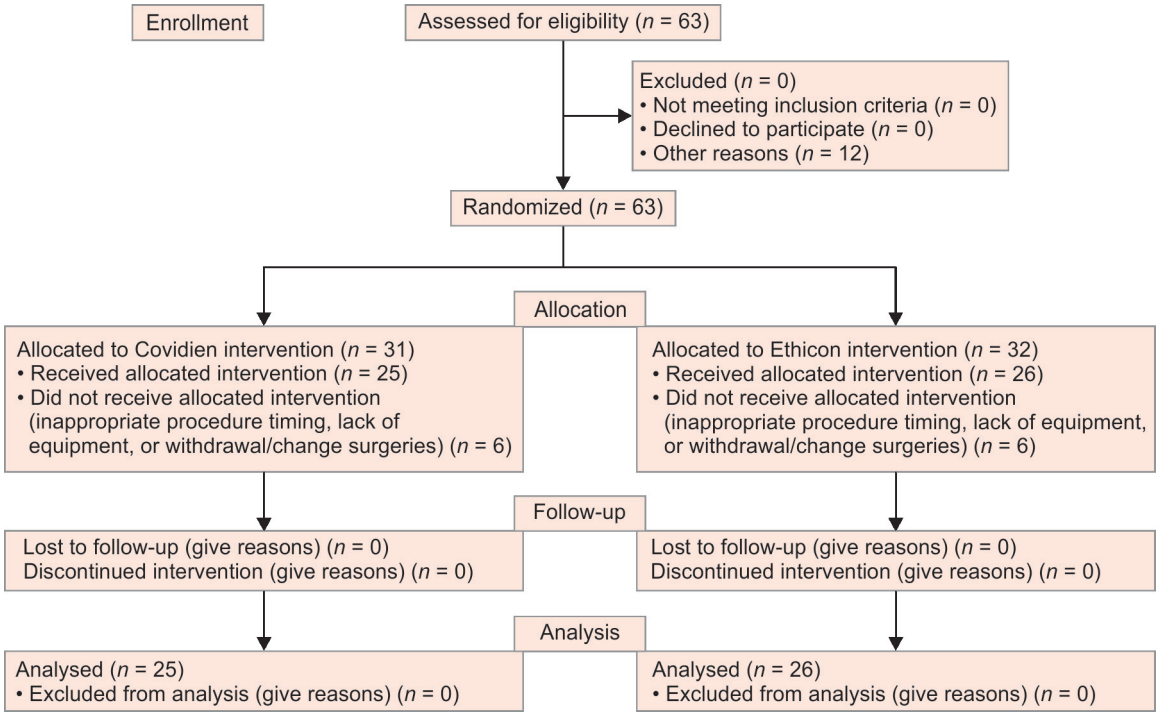
Our primary end points included sleeve creation time (minutes), time to reload (seconds), hemostatic intervention, transfusion, perioperative leak rate, postoperative leak rate, serious complication, mortality rate, and stapler cost (government and commercial rate). The reload time for each staple load was defined as the time from when the stapler exited the trocar until the stapler was ready to be fired again, which we defined as when the stapler was handed back to the surgeon or placed on the Mayo stand if the surgeon was not ready to staple. A physician who was not participating in the operative portion of the case was present to time the surgery. We recorded stapler misfires and results of leak tests, which were determined by the operative surgeon. A Mann-Whitney test was used to compare the distribution of reload times between the two groups.

The cost for civilian vs government institutions for staplers, staple loads, and reinforcements was gathered from the government supply-ordering website and included in the analysis. The cost of each surgery for the Ethicon Echelon was calculated by adding the cost of the color of load, the number of Seamguards that were used, and the cost of the disposable stapler. The Medtronic I-Drive cost was calculated by the cost of the color of load with the pre-attached reinforcement. The cost of the I-Drive stapler was not included as it is not disposable. We did not include the cost of Seamguards or loads that were opened but not used. We performed a pooled *t*-test to compare the two groups.

## Results

We consented 63 patients for the study and randomized participants into the Echelon with Seamguard (ESG) or I-Drive with EndoGIA reinforcement arms (GIA-R) between January 2018 and May 2019—we terminated recruitment due to difficulty obtaining additional participants. There were 31 patients in the ESG arm and 32 in the GIA-R arm. After fall-out, a total of 51 patients remained with 26 in the ESG arm and 25 in the GIA-R arm. All patients in the study completed the Bariatric Pathway at our institution. Their baseline demographics are presented in Table 1. All procedures were completed laparoscopically with no

**Flowchart 1:** Trial profile



intraoperative complications. There were three stapler misfires in the GIA-R arm—a malfunctioning reload requiring physician assist to reload, stapler stuck on staple line, and improper loading resulting in stapler jam. There was one stapler misfire in the ESG arm due to a misfire caused by the Seamguard string not being pulled. All operations had a negative leak test in both the perioperative and postoperative periods.

The primary endpoints are summarized in Table 2. In respect to total time for sleeve creation, 15.63% of sleeve creations using the GIA-R system required a hemostatic intervention compared to 34.38% in the Echelon arm ($p = 0.44$). Half of all staple line bleeds across both arms resolved spontaneously—the remaining half-achieved hemostasis using a surgical clip with one exception requiring a hemostatic agent. All operations did not require blood transfusion and were without serious complications as defined by the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP).[21] There was no mortality in either group.

There was a mean of 5.38 stapler loads used per sleeve gastrectomy in the ESG group and a mean of 4.92 stapler loads used per sleeve gastrectomy in the GIA-R arm ($p = 0.052$). There were 140 stapler loads used in the ESG arm and 123 used in the GIA-R arm. The median reload time was 41.77 seconds in the ESG group 39.78 seconds in the GIA-R group ($p = 0.4242$). The total time for sleeve creation was 12.14 minutes in the ESG arm and 14.26 minutes in the GIA-R arm ($p = 0.04$).

The total cost for the stapler supplies used in each arm was calculated at both the government rate and the commercial rate listed on the government-ordering website. The mean total government cost for the ESG was $2,449.44 and $2,097.66 for the GIA-R ($p = 0.0002$). The mean total commercial cost for the ESG was $1,982.17 and $2,037.25 for the GIA-R ($p = 0.4774$).

**Table 1:** Summary of baseline demographics for study participants

| | *Ethicon Echelon with Seamguard (ESG) (n = 26)* | *Covidien I-Drive with GIA reinforcement (GIA-R) (n = 25)* |
|---|---|---|
| Age | 36.4 | 33.2 |
| Gender | | |
| Male | 5 (20.0%) | 1 (3.8%) |
| Female | 20 (80.0%) | 25 (96.2%) |
| Race | | |
| White | 12 (48.0%) | 15 (57.7%) |
| Black | 5 (20.0%) | 1 (3.8%) |
| Other | 8 (32.0%) | 10 (38.5%) |

## Discussion

The laparoscopic sleeve gastrectomy is now the most commonly performed bariatric surgery in the world, owing to its low rates of morbidity and effectiveness in reducing comorbidities in both the adult and pediatric populations.[22–24] However, complication rates of perioperative bleeding and leakage are still suboptimal, though the use of staple line reinforcement as a mitigation strategy for these morbidities is established.[25] Our institution aimed to perform a head-to-head analysis of the time and cost to reload two commonly used powered linear staplers with staple line reinforcement in laparoscopic sleeve gastrectomies.

In respect of time analysis, there are also significant differences between the reloading mechanism of each platform. The Echelon device has a reloadable, staple containing plastic cartridge that is mechanically secured to the powered unit via a snap-in system. The absorbable polymer reinforcement is subsequently attached. In comparison, the entire shaft of the I-Drive platform is exchanged with each staple reload and each reload cartridge contains the staple line reinforcement already attached. However, the powered unit of the I-Drive platform requires a diagnostic systems check with each cartridge reload whereas the Echelon is ready to fire. In our study, each arm did not have a statistically significant difference in the number of staple reloads required to conduct the operation ($p = 0.052$). Moreover, the time required to reload the staple cartridge and add the staple line reinforcement in the Echelon arm was equivalent to the time needed to change the shaft with the pre-attached staple line reinforcement and perform the diagnostic system check in the I-Drive arm ($p = 0.4242$). However, there was a statistically significant faster time to sleeve creation using the Echelon platform at 12.14 minutes vs the Covidien I-Drive platform at 14.26 minutes ($p = 0.04$). Though the difference in time to sleeve creation was statistically significant, we feel that the mean difference of 2.08 minutes is not clinically significant.

In respect of cost analysis, there are differences between the two powered staplers due to the ancillary purchase required to conduct the operation. While the I-Drive is re-usable after re-processing, the Echelon stapling device is disposable and thus, requires purchase with each operation. The cost of the staple reloads with staple line reinforcement in the I-Drive platform range from $413.94 to $472.36. In comparison, the staple reloads for the Echelon range from $156.60 to $178.26. However, the absorbable polymer reinforcement is purchased separately and costs an additional $164.54 for commercial use and $224.03 for government use. Thus, the mean total cost for conducting a sleeve gastrectomy

**Table 2:** Table of primary end points for the Ethicon Echelon with Seamguard vs Covidien I-Drive with GIA reinforcement

| | *Ethicon Echelon with Seamguard (ESG) (n = 26)* | *Covidien I-Drive with GIA reinforcement (GIA-R) (n = 25)* | *p value* |
|---|---|---|---|
| Sleeve creation time (minutes) | 12.14 | 14.26 | 0.04 |
| Time to reload (seconds) | 41.77 | 39.78 | 0.42 |
| Hemostatic intervention | 34.38% | 15.63% | 0.44 |
| Transfusion | None | None | n/a |
| Perioperative leak rate | None | None | n/a |
| Postoperative leak rate | None | None | n/a |
| Serious complication | None | None | n/a |
| Mortality rate | None | None | n/a |
| Stapler cost (Government rate) | $2,449.44 | $2,097.66 | 0.0002 |
| Stapler cost (Commercial rate) | $1,982.17 | $2,037.25 | 0.48 |

with the Echelon and I-Drive powered staplers was $1,906.25 and $2,037.26 in the commercial sector and $2,356.24 and $2,097.66 in the government sector, respectively. The difference in cost between platforms was not statistically significant with a *p*-value of 0.4774 in the commercial sector, but the cost of the I-Drive platform was significantly lower in the government sector with a *p*-value of 0.0002. Thus, our single-center, randomized control trial demonstrated a significant decrease in cost for the I-Drive platform in the government sector, no difference in the time needed to reload the I-Drive and Echelon platforms, a statistically significant—but not clinically significant—overall time to sleeve creation, and no difference in perioperative or postoperative complications such as leak or bleeding rates.

Our study is not without limitations. Previous studies have evaluated patient characteristics, calibration size, and percentage of excess weight lost,[26] which we did not assess in our analysis. The scope of the data reported focuses on the relatively absent cost and time differential between commercially and publicly available powered linear staplers on the market for laparoscopic sleeve gastrectomies in bariatric surgery. Moreover, the absence of a statistically significant difference in our results is potentially a result of modest sample size due to fall-out and suboptimal recruitment prior to randomization in the study.

## Conclusion

The cost per sleeve gastrectomy at commercial facilities and the time needed to change staple loads for the Medtronic I-Drive and the Ethicon Echelon powered staplers is not significantly different in our military facility.

## Acknowledgments

Though our study is a randomized controlled trial, our data-sharing plan will not include making individual participant data publically available. Because our study was performed at a military facility, individual participant data are considered sensitive government information and will remain classified.

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