Retrospective Comparison of Clinical and Economic Outcomes of Non-Donor Patients Undergoing Radical Nephrectomy Using One of Two Different Linear Stapler Technologies for Transection of the Renal Vessels: Fixed-Height Gripping Surface Reloads vs Variable-Height Reloads

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Purpose: To compare outcomes of non-donor patients undergoing radical nephrectomy using fixed-height gripping surface (FHGS) vs variable-height Tri-Staple™ (VHTS) reloads for transection of the renal vessels.

Patients and Methods: Using the Premier Healthcare Database of US hospital discharge records, we selected non-donor patients undergoing inpatient radical nephrectomy with dates of admission between 1 October 2015, and 31 December 2020 (first=index admission). The primary outcome was in-hospital hemostasis-related complications (hemorrhage, acute posthemorrhagic anemia, and/or procedure to control bleeding) during the index admission. Secondary outcomes included index admission intraoperative injury, blood transfusion, conversion from minimally invasive to open surgery, total hospital costs, length of stay (LOS), discharge status, and mortality as well as 30-day all-cause inpatient readmission. We used stable balancing weights to balance the FHGS and VHTS groups on numerous patient, procedure, and hospital/provider characteristics, allowing a maximum post-weighting standardized mean difference ≤0.01 for all covariates; we also exactly matched the groups on laterality (right vs left kidney) and intended surgical approach (open, laparoscopic, robotic). We used bivariate multilevel mixed-effects generalized linear models accounting for hospital-level clustering to compare the study outcomes between the FHGS and VHTS groups.

Results: After weighting, the FHGS and VHTS groups comprised 2952 and 795 patients, respectively. The observed incidence proportion of the primary outcome of hemostasis-related complications during the index admission was similar between the groups (8.6% for FHGS vs 9.0% for VHTS, difference 0.4% [95% CI −3.2% to 2.5%], P=0.808). Differences between the FHGS and VHTS groups were not statistically significant for any of the secondary outcomes.

Conclusion: Endoscopic surgical staplers have become common for transection of the renal vessels during radical nephrectomy, with FHGS and VHTS being the predominant reload types. In this retrospective study of 3747 non-donor patients undergoing radical nephrectomy, use of FHGS vs VHTS reloads was associated with similar clinical and economic outcomes.

Keywords: radical nephrectomy, hemostasis-related complications, endoscopic surgical staplers, healthcare utilization

Introduction

The adoption of minimally invasive surgical techniques for radical nephrectomy has grown substantially over the past two decades, beginning with the introduction of laparoscopic assistance, followed by robotic-assisted laparoscopic techniques, and most recently, robotically stapled nephrectomy.1,2 Minimally invasive radical nephrectomy, whether
laparoscopic or robotic, has been associated with lower morbidity than open radical nephrectomy, while the laparoscopic
to robotic approaches have demonstrated similar surgical outcomes. As a result of these trends in surgical approach,
endoscopic surgical staplers have become common for transection of the renal vessels during minimally invasive radical
nephrectomy; furthermore, they may also be used in certain circumstances for this task in open radical nephrectomy.

Very early analyses of the US Food and Drug Administration (FDA) Manufacturer and User Facility Device
Experience (MAUDE) database spanning 1992–2007 investigated early trends in the use of such staplers in
nephrectomy. Subsequently, a recently published study presented an analysis of the MAUDE database examining
stapling during hilar ligation in minimally invasive radical nephrectomy from January 1, 2009 to August 1, 2019. Though
these prior studies provide useful insights into various aspects of stapling, they were inherently unable to make
conclusions about comparative outcomes between different stapling devices: the MAUDE database is a passive surveil-
 lance system of medical device reports and the FDA itself warns that for a wide variety of reasons, these data “cannot be
used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices.”

Currently, endoscopic surgical staplers are predominantly produced by two manufacturers: Medtronic, and Ethicon.
Between these two manufacturers, key differentiating features of the staplers are their corresponding reloads. Whereas
Medtronic staplers currently use reloads with variable-height Tri-Staple (VHTS) cartridge faces that are designed to
deliver graduated compression, Ethicon staplers have adopted fixed-height gripping surface reloads (FHGS) with
proprietary pocket extensions to stabilize and hold in place tissue for the deployment of staples with uniform height
(“Gripping Surface Technology”). However, to-date, no study has examined whether different reload formations may be
associated with differences in clinical or economic outcomes in radical nephrectomy.

Therefore, we conducted this retrospective study using a large hospital research database to compare outcomes of
non-donor patients undergoing radical nephrectomy using VHTS vs FHGS reloads for transection of the renal vessels.

**Materials and Methods**

**Data Source**

We extracted the study data from the Premier Healthcare Database® (PHD), which is a population-based hospital
research database that contains administrative records routinely contributed by over 700 US hospitals that are members
of the Premier healthcare performance improvement alliance, representing approximately 25% of annual US inpatient
discharges. This database includes discharge-level information on patient demographics, diagnoses, procedures,
medical supplies, costs, and hospital and provider characteristics. This information is provided in the form of standard-
dized administrative fields, hospital charge master data, and International Classification of Diseases, 10th Revision,
Clinical Modification and Procedure Classification System (ICD-10-CM/ICD-10-PCS) diagnosis and procedure codes
(Supplemental Appendix 1). The PHD has been widely used for epidemiologic and economic research, forming the basis
of over 600 peer-reviewed publications since 2006.

We conducted this study under an exemption from Institutional Review Board oversight for US-based studies using
de-identified healthcare records, as dictated by Title 45 Code of Federal Regulations (45 CFR 46.101(b)(4)).

**Patient Selection**

Using the PHD, we selected non-donor patients undergoing inpatient radical nephrectomy with dates of admission
between October 1, 2015 and December 31, 2020. We designated the first observed inpatient admission meeting these
criteria as the “index admission”, required patients to be at least 18 years of age as of the day of index admission, and
required patients to have at least one hospital charge master record indicating the use of VHTS or FHGS reloads on
the day of the radical nephrectomy. We excluded patients from the study if they met any of the following criteria during
the index admission: primary or secondary diagnosis code for donor nephrectomy; use of the Ethicon Powered Vascular
Stapler (to reduce misclassification of tasks in which staplers were used); use of both VHTS and FHGS reloads; point of
origin was from another institution; major concomitant colorectal resection or procedure involving the vena cava; zero or
negative total hospital costs, room and board, or supply costs.
**Classification of Study Groups**

We classified patients as having either VHTS or FHGS reloads used on the day of the radical nephrectomy based on records in each hospital’s charge master, which is a comprehensive administrative record of billable procedures, equipment fees, supplies, devices, drugs, imaging services, and room and board, among other items. We identified reloads based on model numbers specific to each reload (eg, EGIA60AVM; GST60W) or text descriptions (eg, STAPLES ENDO GIA TRISTAPLE 60MM; STAPLER RELOAD GST 60MM). The list of charge master descriptions identified by the initial search was reviewed by two separate authors to ensure accuracy. Robotic staplers were not included within this analysis. Ultimately, two mutually exclusive groups were established: the VHTS group and the FHGS group.

**Measurement of Outcomes**

This study’s primary outcome was in-hospital hemostasis-related complications, defined as a composite of diagnosis related to intraoperative and postprocedural hemorrhage, hematoma, or seroma of a genitourinary system organ or structure, acute posthemorrhagic anemia, or a procedure code for control of bleeding in the genitourinary tract recorded during the index admission. Secondary outcomes measured during the index admission included diagnosis of intraoperative injury, receipt of blood product transfusion, conversion from minimally invasive to open surgery, total hospital costs from the hospital perspective, length of stay (LOS), discharge status, and mortality, as well as 30-day all-cause inpatient readmission to the same hospital in which the index admission occurred. Information on mortality occurring outside of the hospital is not available in the PHD. See Supplemental Appendix 1 for specific ICD-10-CM/PCS diagnosis and procedure codes used to measure the study outcomes, where applicable.

Total hospital costs were standardized to 2020 US Dollars based on the Medical Care component of the Consumer Price Index. In the PHD, hospital costs are reported directly by the hospitals from which data are sourced in this database. Costs are determined based on each hospital’s own charge master. Analyses of all-cause hospital readmissions were limited to patients in Institutions that continued to contribute data to the Premier Healthcare Database through or beyond 30 days after the index admission.

**Measurement of Covariates**

We measured study covariates using records from the index admission. Patient demographics included age, sex, marital status, race, payer type, and year of index admission. Patient clinical characteristics included the Charlson Comorbidity Index Score,11 Elixhauser’s comorbidities,12 and other selected comorbidities, encompassing individual flags for the following: adhesions, congestive heart failure, cardiac dysrhythmias, valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hypertension uncomplicated, hypertension complicated, other neurological disorders, chronic pulmonary disease, diabetes uncomplicated, diabetes complicated, hypothyroidism, renal failure, liver disease, metastatic cancer, solid tumor without metastasis, rheumatoid arthritis/collagen, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, nutritional anemia, deficiency anemia, nutritional and metabolic disorders, alcohol abuse and disorders, drug abuse, psychoses, and depression. Diagnoses for comorbidities could not have a Present on Admission indicator of “No”.

Procedural characteristics included surgical indication (renal cell carcinoma, other cancer, or non-cancer primary diagnosis for the index admission), intended surgical approach (laparoscopic, robotic, open), laterality (left, right, bilateral), elective vs non-elective procedure, and individual flags for the following concomitant secondary procedures that were observed with >1% frequency in the study patients: ureter/bladder resection, ureter/bladder excision, procedures related to the spleen, procedures related to the lymph nodes, hepatopancreatobiliary excision, gastrointestinal excision, procedures related to the adrenal gland, and procedures related to adhesions.

Hospital/provider characteristics included urban vs rural hospital, teaching vs non-teaching hospital, hospital bed size category, annual radical nephrectomy volume, and surgical specialty of the physician performing the procedure.

**Statistical Analyses**

We used stable balancing weights (SBW), an optimization-based analogue to inverse propensity score weighting, to balance all study covariates listed above.13 SBW directly targets covariate balance by treating weighting as an
optimization problem, whereby an objective function is maximized subject to constraints: the objective function is to find the mathematically guaranteed weights of minimum variance (leading to the largest weighted sample size) subject to researcher-specified covariate balance constraints (ie, a prespecified maximum standardized mean difference [SMD] for each covariate between the study groups).

SBW weighting procedure is performed using R statistical software (www.r-project.org) and the -sbw- and -quadprog- packages. To find the optimal SMD threshold, we used a “grid search”, whereby the smallest overall SMD threshold is chosen relative to resultant sample size loss. An SMD value ≤0.10 is indicative of good balance. The resultant SMD threshold was 0.01. We also matched patients exactly on intended surgical approach and laterality. We applied the SBWs to the VHTS group, thereby re-weighting the VHTS group to appear nearly identical to the FHGS group.

We compared outcomes between the VHTS and FHGS groups using bivariate multilevel mixed-effects generalized linear models with robust standard errors, wherein patients were treated as nested within hospitals and the weights from the SBW procedure were incorporated as probability weights. A logit link and binomial error distribution were used when comparing binary outcomes, a log link and negative binomial error distribution was used when comparing length of stay. \( P<0.05 \) was set as the threshold for statistical significance.

Results

Patient and Hospital/Provider Characteristics

Before weighting, there were 2952 patients in the FHGS group and 1032 in the VHTS group, with substantial differences on several weighting covariates (Figure 1). After weighting, all 2952 patients in the FHGS group and 795 patients in the VHTS group were retained for analysis, coming from a total of 165 individual hospitals. All post-weighting standardized mean differences were ≤0.01, indicating excellent covariate balance between the study comparison groups.

Tables 1–3, and 4 display information on post-weighting patient demographics, patient clinical characteristics, procedure characteristics, and hospital/provider characteristics, respectively. Overall, the mean patient age was 63 years, 41% were female, and most (80%) were of white race (Table 1). The five most common comorbidities were

![Figure 1 Standardized mean differences before vs after weighting.](https://doi.org/10.2147/MDER.S372629)

Notes: "Each marker along the horizontal axis represents a variable on which the two groups were balanced through stable balancing weights; after weighting, all standardized mean differences were ≤0.01 indicating excellent covariate balance."
hypertension (69%), diabetes (28%), obesity (22%), renal failure (22%), and chronic pulmonary disease (14%) (Table 2). Most (57%) patients’ surgical indication was for renal cell carcinoma, with robotics being used in 39% of the procedures, and the majority (91%) of admissions being elective (Table 3). Patients were predominantly treated in urban hospitals (96%) and nearly all (96%) underwent surgery by a urologist (Table 4).

### Analyses of Primary Outcome

Figure 2 shows the results to the analyses of the primary outcome of in-hospital hemostasis-related complications during the index admission. The incidence proportion of the primary outcome of hemostasis-related complications during the

### Table 1 Patient Demographic Characteristics After Weighting

|                     | FHGS       | VHTS       | SMD*   |
|---------------------|------------|------------|--------|
| N                   | 2952       | 795        |        |
| %                   | 100.00%    | 100.00%    |        |

| Age category, N/%   | FHGS       | VHTS       | SMD*   |
|---------------------|------------|------------|--------|
| 18–44               | 284        | 74         | 0.010  |
| 45–54               | 449        | 118        | 0.010  |
| 55–64               | 754        | 205        | 0.005  |
| 65–74               | 923        | 249        | 0.000  |
| 75 Plus             | 542        | 149        | 0.010  |

| Female, N/%         | FHGS       | VHTS       | SMD*   |
|---------------------|------------|------------|--------|
| 1223                | 41.4%      | 325        | 0.010  |

| Married, N/%        | FHGS       | VHTS       | SMD*   |
|---------------------|------------|------------|--------|
| 1676                | 56.8%      | 447        | 0.010  |

| Race, N/%           | FHGS       | VHTS       | SMD*   |
|---------------------|------------|------------|--------|
| Black               | 265        | 74         | 0.010  |
| White               | 2353       | 634        | 0.001  |
| Other/unknown       | 334        | 87         | 0.010  |

| Payer category, N/% | FHGS       | VHTS       | SMD*   |
|---------------------|------------|------------|--------|
| Commercial          | 1001       | 273        | 0.010  |
| Medicare            | 1587       | 423        | 0.010  |
| Medicaid            | 163        | 46         | 0.010  |
| Other               | 201        | 53         | 0.008  |

| Year of index admission, N/% | FHGS       | VHTS       | SMD*   |
|-----------------------------|------------|------------|--------|
| 2015 (October onwards)      | 56         | 16         | 0.010  |
| 2016                        | 233        | 65         | 0.010  |
| 2017                        | 414        | 114        | 0.010  |
| 2018                        | 669        | 177        | 0.010  |
| 2019                        | 893        | 241        | 0.006  |
| 2020                        | 687        | 182        | 0.010  |

*Note:* A standardized mean difference <0.10 is considered indicative of good covariate balance.

**Abbreviations:** FHGS, fix-height gripping surface reload; SMD, absolute standardized mean difference; VHTS, variable-height Tri-Staple reload.
|                                | FHGS          | VHTS          | SMD* |
|--------------------------------|---------------|---------------|------|
| **N**                          | 2952          | 795           |      |
| **%**                          | 100.00%       | 100.00%       |      |
| **CCI score, N/%**             |               |               |      |
| 0                              | 426           | 112           | 0.010|
| 1–2                            | 1163          | 309           | 0.010|
| 3–4                            | 823           | 225           | 0.009|
| 5+                             | 540           | 149           | 0.010|
| **Comorbidities, N/%**         |               |               |      |
| Adhesions                      | 207           | 54            | 0.010|
| Alcohol abuse and related disorders | 84       | 21            | 0.010|
| Cardiac arrhythmias/dysrhythmia | 324          | 85            | 0.010|
| Chronic pulmonary disease      | 415           | 112           | 0.001|
| Coagulopathy                   | 79            | 20            | 0.010|
| Congestive heart failure       | 190           | 53            | 0.010|
| Deficiency anemia              | 70            | 20            | 0.010|
| Depression                     | 293           | 77            | 0.010|
| Diabetes, complicated          | 349           | 91            | 0.010|
| Diabetes, uncomplicated        | 482           | 133           | 0.010|
| Fluid and electrolyte disorders | 242          | 67            | 0.006|
| Hypertension, complicated      | 645           | 170           | 0.010|
| Hypertension, uncomplicated    | 1393          | 375           | 0.001|
| Hypothyroidism                 | 344           | 90            | 0.010|
| Liver disease                  | 83            | 24            | 0.010|
| Malnutrition                   | 39            | 11            | 0.010|
| Metastatic cancer              | 175           | 49            | 0.010|
| Nutritional and metabolic disorders | 115       | 29            | 0.010|
| Nutritional anemia             | 90            | 25            | 0.007|
| Obesity                        | 641           | 176           | 0.010|
| Other neurological disorders   | 82            | 23            | 0.010|
| Peripheral vascular disorders  | 115           | 29            | 0.010|
| Pulmonary circulation disorders | 39           | 10            | 0.010|
| Renal failure                  | 639           | 170           | 0.006|
| Rheumatoid arthritis           | 61            | 17            | 0.002|

(Continued)
### Table 2 (Continued).

|                         | FHGS          | VHTS          | SMD*  |
|-------------------------|---------------|---------------|-------|
|                         | N     | %      | N     | %      |       |
| Valvular disease        | 2952  | 100.00%| 795   | 100.00%| 0.010 |
| Weight loss             | 78    | 2.6%   | 22    | 2.8%   | 0.010 |

Note: *A standardized mean difference <0.10 is considered indicative of good covariate balance.

**Abbreviations:** CCI, Charlson comorbidity index; FHGS, fix-height gripping surface reload; SMD, absolute standardized mean difference; VHTS, variable-height Tri-Staple reload.

### Table 3 Procedural Characteristics After Weighting

|                         | FHGS          | VHTS          | SMD*  |
|-------------------------|---------------|---------------|-------|
|                         | N     | %      | N     | %      |       |
| Surgical indication**, N/% |     |       |       |       |       |
| Renal cell carcinoma    | 1678  | 56.8%  | 453   | 57.0%  | 0.002 |
| Other cancer            | 331   | 11.2%  | 87    | 10.9%  | 0.010 |
| Non-cancer diagnosis    | 943   | 31.9%  | 255   | 32.1%  | 0.002 |
| Laterality, N/%         |       |       |       |       |       |
| Left                    | 1506  | 51.0%  | 406   | 51.0%  | 0.000 |
| Right                   | 1402  | 47.5%  | 378   | 47.5%  | 0.000 |
| Bilateral               | 44    | 1.5%   | 11    | 1.5%   | 0.000 |
| Intended surgical approach, N/% |     |       |       |       |       |
| Laparoscopic            | 938   | 31.8%  | 253   | 31.8%  | 0.000 |
| Robotic                 | 1142  | 38.7%  | 308   | 38.7%  | 0.000 |
| Open                    | 872   | 29.5%  | 234   | 29.5%  | 0.000 |
| Admission type, N/%     |       |       |       |       |       |
| Elective                | 2683  | 90.9%  | 720   | 90.6%  | 0.010 |
| Non-elective            | 269   | 9.1%   | 75    | 9.4%   | 0.010 |
| Concomitant procedures***, N/% |     |       |       |       |       |
| Adhesion procedure      | 149   | 5.0%   | 40    | 5.1%   | 0.010 |
| Adrenal gland procedure | 248   | 8.4%   | 65    | 8.1%   | 0.010 |
| Gastrointestinal excision | 48   | 1.6%   | 12    | 1.5%   | 0.006 |
| Hepatopancreatobiliary excision | 36   | 1.2%   | 9     | 1.1%   | 0.010 |
| Concomitant lymph node procedure | 310 | 10.5%  | 86    | 10.8%  | 0.010 |
| Spleen procedure        | 37    | 1.3%   | 11    | 1.4%   | 0.010 |

(Continued)
index admission was similar between the groups (8.6% for FHGS vs 9.0% for VHTS; the risk difference between the FHGS group and the VHTS group was −0.4% (95% confidence interval −3.2% to 2.5%), \( P = 0.808 \). Although hemostasis-related complications represented a composite outcome, events were primarily driven by diagnosis of acute posthemorrhagic anemia: of the patients with a hemostasis-related complication, 98.8% had a diagnosis of acute posthemorrhagic anemia, whereas only 4.5% (0.4% of the patients overall) had a diagnosis related to intraoperative or postprocedural hemorrhage, hematoma, or seroma of a genitourinary system organ or structure; there was one case of procedure for control of bleeding in the genitourinary tract, within the FHGS group (\( P = 0.318 \) vs VHTS). Results of analyses of the primary outcome before weighting (ie, unadjusted analyses) are shown in Supplemental Table 1.

Table 3 (Continued).

|                      | FHGS   |          | VHTS   |          | SMD*   |
|----------------------|--------|----------|--------|----------|--------|
|                      | N      | %        | N      | %        |        |
| Ureter or bladder resection | 2952   | 100.00%  | 795    | 100.00%  |        |
|                      | 326    | 11.0%    | 90     | 11.4%    | 0.010  |
| Ureter or bladder excision | 236    | 8.0%     | 61     | 7.7%     | 0.010  |

Notes: *A standardized mean difference <0.10 is considered indicative of good covariate balance. **Primary diagnosis of the index admission. ***Concomitant secondary procedures that were observed with >1% frequency in the study patients.

Abbreviations: FHGS, fix-height gripping surface reload; SMD, absolute standardized mean difference; VHTS, variable-height Tri-Staple™ reload.

Table 4 Hospital/Provider Characteristics After Weighting

|                      | FHGS   |          | VHTS   |          | SMD*   |
|----------------------|--------|----------|--------|----------|--------|
|                      | N      | %        | N      | %        |        |
| Urban hospital, N/% | 2845   | 96.4%    | 765    | 96.2%    | 0.010  |
| Teaching hospital, N/% | 1233  | 41.8%    | 336    | 42.3%    | 0.010  |
| Hospital bed size, N/% | 331   | 11.2%    | 92     | 11.5%    | 0.008  |
| 000–199              |        |          |        |          |        |
| 200–299              | 394    | 13.3%    | 103    | 13.0%    | 0.010  |
| 300–499              | 1377   | 46.6%    | 367    | 46.2%    | 0.010  |
| 500+                 | 850    | 28.8%    | 233    | 29.2%    | 0.010  |
| Annual RN volume, N/% | 2042  | 69.2%    | 554    | 69.6%    | 0.010  |
| 0–100                | 910    | 30.8%    | 241    | 30.4%    | 0.010  |
| Procedural physician specialty, N/% | 2844 | 96.3% | 764 | 96.2% | 0.010 |
| Urology              | 108    | 3.7%     | 31     | 3.8%     | 0.010  |

Note: *A standardized mean difference <0.10 is considered indicative of good covariate balance.

Abbreviations: FHGS, fix-height gripping surface reload; SMD, absolute standardized mean difference; VHTS, variable-height Tri-Staple™ reload; RN, radical nephrectomy.
Analyses of Secondary Outcomes

Table 5 shows the results of the analyses of secondary outcomes. Differences between the FHGS and VHTS groups were not statistically significant for any secondary outcome: intraoperative injury (no events in either group); blood transfusion (6.0% for FHGS vs 8.1% for VHTS, P=0.335); conversion from minimally invasive to open surgery (1.7% for FHGS vs 1.5% for VHTS, P=0.794); index admission mean total hospital costs ($13,730 for FHGS vs $14,470 for VHTS, P=0.705); index admission mean length of stay (3.7 days for FHGS vs 4.1 days for VHTS, P=0.153); discharge to home (94.4% for FHGS vs 94.8% for VHTS, P=0.735); mortality (0.58% for FHGS vs 0.53% for VHTS, P=0.905); and, 30-day all-cause inpatient readmission to the same hospital in which the index admission occurred (6.2% for FHGS vs 6.0% for VHTS, P=0.866). Results of analyses of the secondary outcomes before weighting (ie, unadjusted analyses) are shown in Supplemental Table 1.

### Table 5 Analyses of Secondary Outcomes

| Outcome                          | FHGS | VHTS | Mean Incremental Difference | Lower 95% CI | Upper 95% CI | P    |
|----------------------------------|------|------|-------------------------------|--------------|--------------|------|
| Intraoperative injury*           | 0.0% | 0.0% | n/a                           | n/a          | n/a          | n/a  |
| Blood transfusion                | 6.0% | 8.1% | -2.1%                         | -6.3%        | 2.2%         | 0.335|
| Conversion to open surgery       | 1.7% | 1.5% | 0.2%                          | -1.2%        | 1.6%         | 0.794|
| Index admission total costs (mean)| $13,740 | $14,470 | -$730                         | -$4510       | $3049        | 0.705|
| Index admission length of stay (mean)| 3.70 | 4.06 | -0.36                         | -0.87        | 0.14         | 0.153|
| Discharge to home**              | 94.4%| 94.8%| -0.4%                         | -2.4%        | 1.7%         | 0.735|
| Mortality during index admission | 0.53%| 0.58%| 0.05%                         | -0.07%       | 0.08%        | 0.905|
| 30-Day inpatient readmission***  | 6.2% | 6.0% | 0.2%                          | -2.2%        | 2.6%         | 0.866|

**Notes:** *No patient had diagnosis of intraoperative injury. **Discharge to home setting vs another setting such as skilled nursing facility. ***All-cause inpatient readmission to the same hospital in which the index admission occurred.

**Abbreviations:** FHGS, fix-height gripping surface reload; VHTS, variable-height Tri-Staple reload.

### Figure 2 Analysis of primary outcome.*

**Notes:** *The primary outcome = hemostasis-related complications – was defined as a composite of diagnosis related to intraoperative and postprocedural hemorrhage, hematoma, or seroma of a genitourinary system organ or structure, acute posthemorrhagic anemia, or a procedure code for control of bleeding in the genitourinary tract recorded during the index admission; the mean incremental difference between the groups was -0.4% (95% confidence interval: -3.2% to 2.5%), P=0.808.

**Abbreviations:** FHGS, fix-height gripping surface reload; VHTS, variable-height Tri-Staple reload.
Discussion

This study reports the first comparative effectiveness assessment between FHGS and VHTS reloads for transection of the renal vessels among non-donor patients undergoing radical nephrectomy. We found that use of FHGS vs VHTS reloads for transection of the renal vessels was not associated with significantly different clinical or economic outcomes.

Hemostasis-related complications were driven primarily by diagnoses of acute post-hemorrhagic anemia, with <0.5% of the patients having a diagnosis for hemorrhage, hematoma, or seroma of a genitourinary system organ or structure. The rate of blood transfusion (6.0% for FHGS and 8.1% for VHTS) fell well within the range reported in prior literature, which is as low as 4% to as high as 24% for radical nephrectomy.15,16

The present study’s findings of statistical parity in outcomes between these reload technologies is based on an epidemiologically appropriate database and statistical methodology for comparative effectiveness research. A prior MAUDE database analysis reported that Ethicon staplers (agnostic to reload type) were associated with ostensibly more complications when not considering a population denominator.5 However, because differences in the real-world number (denominator) of staplers used were unknown, the complication rate could not be calculated. Indeed, whereas our query of the database yielded 2952 patients in the FHGS group, it yielded only 1032 in the VHTS group; therefore, under the circumstances of no differences in outcomes between these technologies, the crude number of events would be expected to be approximately 2.9 times higher in the FHGS vs VHTS group, a difference that is larger than what was reported in the MAUDE data. Thus, it is very plausible that the prior findings were primarily a reflection of differences in the volume of staplers used across manufacturers.

To our knowledge, only one prior study by Rawlins and colleagues had previously compared clinical and economic outcomes between FHGS and VHTS reloads, specifically among patients undergoing laparoscopic sleeve gastrectomy using powered staplers.17 They found that the ECHELON FLEX™ GST system (with FHGS) was associated with a lower rate of hemostasis-related complications as compared with the Signia™ Stapling System (with VHTS reloads). In the present study, the incidence proportion of hemostasis-related complications was numerically lower for FHGS vs VHTS reloads (8.6% vs 9.0%), but this difference did not reach statistical significance. A potential driver of the differences between the present and prior study is that radical nephrectomy is a more complex procedure than laparoscopic sleeve gastrectomy, performed for multiple different potential surgical indications and often involving concomitant procedures on adjacent anatomy, thereby increasing the potential for unmeasured variability to cloud the extent to which individual differences in the outcomes associated with devices can be identified in retrospective observational data.

The primary strengths of this study are that it is based on a large cohort of 3747 patients, coming from 165 hospitals, using a data source that allows for epidemiologic inferences about comparative outcomes, and using a statistical methodology that resulted in extremely well-balanced cohorts. However, this study also has important limitations. First, although we used a rigorous statistical methodology to balance the cohorts on measurable characteristics, there is no single data source (aside from a randomized controlled trial) that can rule out the potential for residual confounding from unmeasured factors such as the skill of the surgeon and their supporting clinical team, the complexity of a patient’s anatomy, the extent of a patient’s disease, use of concomitant medications that may influence hemostasis-related bleeding risk, or other potential factors. For example, there may be a wide level of variability in surgeon preference regarding the concomitant use of energy devices or other forms of vascular pedicle ligation, such as surgical ligation; furthermore, information on whether the renal hilar vessels were stapled separately or en bloc is unavailable in the PHD. Additionally, the ICD-10-PCS diagnosis coding system delineates between metastatic and non-metastatic cancer, on which the two groups were well balanced, but does not provide specific information on cancer stage, tumor size, and other detailed oncological factors, which could have influenced outcomes such as blood loss. Second, the identification of FHGS and VHTS reloads was based upon the hospital charge master, which may be subject to misclassification if the wrong product was entered in the charge master. Third, identification of hemostasis-related complications using ICD-10-CM/PCS coding is also subject to misclassification resulting from potential administrative coding or documentation errors. Finally, due to severe sample size constraints, we were unable to examine donor nephrectomies and nephrectomies...
that were robotically stapled; future studies are needed to confirm and extend the present study’s findings to these patient groups and technologies.

**Conclusion**
Endoscopic surgical staplers have become common for transection of the renal vessels during radical nephrectomy, with FHGS and VHTS being the predominant reload types. In this retrospective study of 3747 non-donor patients undergoing radical nephrectomy, use of FHGS vs VHTS reloads was associated with similar clinical and economic outcomes.

**Abbreviations**
FDA, US Food and Drug Administration; FHGS, fixed-height gripping surface reload; ICD-10-CM/ICD-10-PCS, International Classification of Diseases, 10th Revision, Clinical Modification and Procedure Classification System diagnosis and procedure codes; LOS, length of stay; MAUDE, Manufacturer and User Facility Device Experience; PHD, Premier Healthcare Database®; SMD, standardized mean difference; SBW, stable balancing weights; VHTS, variable-height Tri-Staple reload.

**Data Sharing Statement**
The Premier Healthcare Database is available for commercial license from Premier Inc.

**Ethics Approval and Informed Consent**
We conducted this study under an exemption from Institutional Review Board oversight for US-based studies using de-identified healthcare records, as dictated by Title 45 Code of Federal Regulations (45 CFR 46.101(b)(4)).

**Author Contributions**
All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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**Disclosure**
Stephen Johnston, Barbara Johnson, Philippe Grange, Sanjoy Roy, and Esther Pollack are employees and stockholders of Johnson & Johnson. Divya Chakke is employed by Mu Sigma, which was paid by Johnson & Johnson to conduct data programming and statistical analyses. The authors report no other conflicts of interest in this work.

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