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Clinical Summary

Medtronic provides the following synopsis of a manuscript showing the effectiveness of bedside staplers in bariatric robotic procedures.

TITLE	Effectiveness of bedside staplers in bariatric robotic procedures
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WHY THIS IS IMPORTANT

Bedside stapling is a technique in which laparoscopic or endoscopic staplers (e.g. Signia™ with Tri-Staple™ reloads manufactured by Medtronic) are used during robotic assisted surgery rather than staplers integrated on the daVinci robotic system (e.g. SureForm staplers manufactured by Intuitive Surgical (ISRG)). There are strong clinical and economic reasons why surgeons and the Operating Room (OR) staff prefer using bedside stapling.

This study evaluates the effectiveness of bedside staplers in comparison to integrated Intuitive Surgical Robotics Group SureForm (ISRG SureForm) robotic staplers in bariatric robotic procedures.

METHODS

- This study reviewed patient outcome data from PINC AI Healthcare Data (PHD). PHD is a US hospital based, all-payer data representing 25% of annual US inpatient admissions.
- Patients who underwent robotic sleeve gastrectomy or robotic gastric bypass elective procedures throughout 2021 were eligible for inclusion in this study.
- Staplers were identified using the hospital billing data.

- The bedside stapling group (BS) utilized Ethicon (JNJ) and Medtronic (MDT) staplers. This group was separated further to evaluate MDT staplers alone, classified as manual/intelligent bedside staplers (MIBS).
- The integrated robotic stapler group utilized SureForm staplers on the da Vinci robot.
- Outcomes evaluated included – clinical outcomes (blood transfusion, bleeding, anastomotic leak, intensive care unit (ICU) visits, and 30-day urgent and emergent readmission) and healthcare resource utilization (operating room (OR) time, total hospitalization costs (in US dollars), and length of hospital stay).
- Multivariable general linear mixed models (GLMMs) with respective gamma or binomial distribution and log-link function were used to obtain the variations of adjusted outcomes.
- Two additional methods (including Propensity Score Matching or PSM) were used to conduct sensitivity analysis.

RESULTS:

- After applying appropriate inclusion and exclusion criteria, 7,268 patients were included (n=1,603 bedside stapling patients (included 863 MIBS cases), n=5,665 robotic stapler-only patients).
- The statistically significat results from 2 key comparisons performed are as follow:
  1. When comparing bedside staplers (BS) vs. ISRG SureForm stapler (RS), authors found that:
     a. ISRG SureForm staplers were associated with 8.5 times the risk (odds ratio) of ICU stays compared to bedside staplers (p=0.004).
     b. ISRG SureForm staplers were associated with 19 minutes longer OR time compared to bedside staplers (p<0.001).
     c. ISRG SureForm staplers were associated with higher total hospitalization costs ($1273) compared to bedside staplers (p<0.001).
     d. ISRG SureForm staplers were associated with 0.26 days shorter length of stay compared to bedside staplers (p<0.001).
  2. When comparing Medtronic staplers (MIBS) vs. ISRG SureForm staplers (RS), authors found that:
     a. ISRG SureForm staplers were associated with 17.2 times the risk (odds ratio) of ICU stays compared to Medtronic staplers used by the bedside (p=0.044).
     b. ISRG SureForm staplers were associated with 31.6 minutes longer OR time compared to Medtronic staplers used by the bedside (p<0.001).
     c. ISRG SureForm staplers were associated with higher total hospitalization costs ($2670) compared to Medtronic staplers used by the bedside (p<0.001).

a. ISRG SureForm staplers were associated with 0.16 days shorter length of stay compared to Medtronic staplers used by the bedside (p=0.002).

Results were broadly consistent when sensitivity analysis was performed.

STUDY LIMITATIONS

- This is a database driven study that establishes associations between products and outcomes. This study does not prove any causal linkages. Causal linkages are typically proved by randomized clinical studies. These studies are extremely difficult to execute with different stapler manufacturers.
- The hospital-based database does not include the granularity of staple load (height) or presence of staple line reinforcement. These factors can affect the formation of staples and outcomes; we were unable to account for these two factors.
- This study does not account for staple selection driven by hospital contracting.

CONCLUSION

The study's analysis of clinical data suggests that bedside stapling is associated with lower likelihood of ICU stays, shorter OR times, and lower cost than ISRG SureForm robotic stapling in bariatric robotic procedures. These results were consistent with the findings when comparing Medtronic staplers to ISRG SureForm staplers. This evidence supports the use of Medtronic bedside staplers from a clinical and economic perspective.

****THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS MANUSCRIPT****