Safety and feasibility of Single Port Robotic Right colectomies – Results of an Investigator-Initiated Investigational Device exemption study using the Intuitive Da Vinci SP Platform

Ankit Sarin, MD MHA, Katie Barnes, Amy Shui, MA , Yukino Nakamura, Daniel Hoffman, MD, Fernanda Romero-Hernandez, MD, Hueylan Chern, MD

UCSF Department of Surgery

Introduction

- **Minimally-invasive techniques** for **colectomy** have historically involved the use of multiple ports, with **single-port laparoscopic surgery limited** by **technical challenges**.
- The **Intuitive Da Vinci Single Port (SP) robotic platform** overcomes a number of these challenges.
- We designed a study to assess the **safety** and **feasibility** of the SP platform in performing segmental colectomies.

Methods

- Single center, prospective, open-label, investigator-initiated, non-randomized, interventional, case-control study.
- We compared the **safety and quality event (SQ Event) rate** between patients who underwent right colectomies using the **SP platform** with those who underwent right colectomies using the standard **multiport platform (Xi)**.
- **Fisher's exact** and exact **Wilcoxon rank-sum tests** were used to compare both groups.

Results

- We compared **five patients** undergoing a right colectomy using the **SP platform** with **twenty-five patients** who had undergone a right colectomy using the **Xi Platform.**
- Indications for SP right colectomy included: two patients with **colon cancer**, one with **appendiceal goblet cell carcinoma**, one with **appendiceal** orifice **adenocarcinoma** and one with intermittent **cecal volvulus**.

Figure 1. Right colectomy single port and instrument setup of the Intuitive Da Vinci Single Port (SP) robotic platform

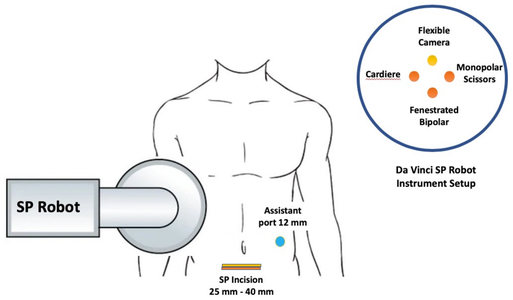
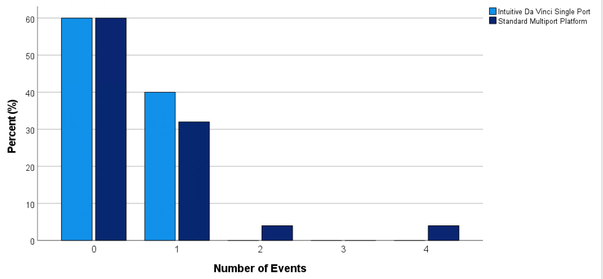


Table 1. Perioperative Outcomes in Right Colectomies Comparing Single Port (SP) vs. Multiport (Xi) Platforms

	SP	Xi
Safety and Quality Event	(n = 5)	(n = 25)
Conversion to open or laparoscopic procedure	0 (0%)	0 (0%)
Intraoperative EBL > 200 mL	0 (0%)	0 (0%)
Operative time > 90th percentile of cohort [a]	0 (0%)	9 (36%)
Positive pathological margins (if applicable)	0 (0%)	0 (0%)
Fragmented specimen (if applicable)	0 (0%)	0 (0%)
ICU Stay	0 (0%)	1 (4%)
Post-procedure LOS > 90th percentile of cohort [a]	0 (0%)	1 (4%)
30-day reoperation	0 (0%)	0 (0%)
Post-procedure pain > 90th percentile of cohort [a]	1 (20%)	0 (0%)
Postoperative complication as defined by NSQIP [b] (if applicable)	1 (20%) [c]	3 (12%) [d]

[a] Cohort is all patients with robotic and laparoscopic procedures with matching CPT code (right colectomy)
[b] Defined SSI, DVT, PE, readmission, postoperative blood transfusion or anastomotic leak
[c] Postoperative DVT requiring therapy
[d] Postoperative blood transfusion (within 72 hours of surgery start time)

Figure 2. Number of Perioperative Events in Right Colectomies Comparing Single Port (SP) vs. Multiport (Xi) Platforms



Conclusion/Implications

- This study represents one of the first FDA-approved, investigator-initiated use of the Da Vinci SP in colorectal surgeries.
- This preliminary safety and quality study shows that relevant safety and quality events do not differ significantly between the use of the traditional multiport (Xi) robotic platform and the novel single port (SP) platform when used for right colectomies.
- The role of the single port platform and its value in colorectal surgery is still being defined.

Author Disclosures:

- AS is a consultant for several robotic companies including Johnson &Johnson, Noah Medical and Neptune Medical.
- No other disclosures

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