

Quantify the Impact (QTI): Cholecystectomy

The potential clinical and economic value of robotic-assisted surgery using da Vinci systems

Background information

Intent

The intent of this presentation is to provide **directional data**.

This presentation must **not be considered as a substitute for data from published clinical study(ies)** or data from a comprehensive literature review for inclusion of all relevant outcomes.

We encourage all key stakeholders (e.g., surgeons, hospital executives, hospital robotic coordinators, etc.) to **review all available published materials as well as their own data** in order to make an informed decision.

Clinical outcomes: Published literature

To provide a **complete, fair, and balanced view of the clinical literature**, Intuitive identified the following set of nine standard clinical outcomes to be reported for published literature, along with outcomes pertaining to primary intent of the publication.

- Transfusion and/or estimated blood loss
- Operative time
- Length of hospital stay
- Conversion rate (vs. laparoscopy, only)
- Complication rate (30 days or other) (intraoperative and/or postoperative)
- Readmission rate (30 days or other)
- Reoperation rate (30 days or other)
- Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging
- Perioperative mortality (30 days)

Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Case-specific disclosures will be added on applicable slides if an outcome is an **atypical experience** for that region. (The experience is not depicted by the majority of the physicians and/or published evidence for a given surgical procedure in that region, when utilizing a given product for the claim.)

Clinical outcomes: Unpublished

Outcome measures reported from unpublished data are selected based on the surgeon's interests and availability of relevant data. Not all outcomes affecting the patient, hospital or surgeon practice may be reported here. When available, all standard nine clinical outcomes must be reported.

- The surgeon-provided data shown here may be **aggregated level data, or analysis of encounter level data** from the surgeon. Data is not collected under formalized study and is neither verified or validated by Intuitive. **For encounter level data, agreement with a hospital is required before receiving the data.**
- The data comparison shown here is **not case-matched for patient complexity and/or disease status**, unless otherwise indicated, and may not be comparable across these surgical modalities.
- As such, this data is neither **peer reviewed nor published** and may or may not be reproducible or generalizable. Henceforth, should be considered as **informational only and is not conclusive.**
- Please refer to the **background slide** for additional information on the unpublished data

Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

- Case specific disclosure will be added on applicable slides if an outcome is of **“Atypical experience”** for that region (The experience is not depicted by the majority of the physicians/published evidence for a given surgical procedure in that region when utilizing a given product for the claim)

Economic outcomes

From a hospital perspective, clinical benefits may result in the potential cost savings discussed here; however, these clinical benefits and costs may vary per hospital, be higher or lower than mentioned during this presentation, and have not been published or peer-reviewed.

The implementation of a robotic-assisted surgery (RAS) program using da Vinci systems is practice- and hospital-specific. Results may vary. Past customer experience does not imply any guarantee of results in practice or program success.

Cost estimates seen here have been independently generated by Intuitive using cost modeling methodology based on a review of relevant peer-reviewed publications and/or national averages. This cost modeling methodology has not been published or peer-reviewed.

Cost calculations include intraoperative instrument and accessory costs, if indicated. Costs related to da Vinci system acquisition, yearly service costs, and other intraoperative and post-operative hospital costs are not included/considered, unless otherwise indicated.

When considering cost-effectiveness of an advanced technology like the da Vinci system, we recommend that hospitals perform a full cost-benefit analysis, considering not just the operating room costs but also the costs associated with hospital stays, procedure-related complications, and hospital re-admissions.

Background information

Published literature

In order to provide benefit and risk information, Intuitive reviews the **highest available level of evidence** on representative procedures.

Intuitive strives to provide a **complete, fair, and balanced view of the clinical literature**. However, a quoted article may not be reflective of the broader literature and our materials should not be seen as a substitute for a comprehensive literature review for inclusion of all potential outcomes.

We encourage patients and physicians to **review the original publications and all available literature** in order to make an informed decision. Clinical studies are available at pubmed.gov.

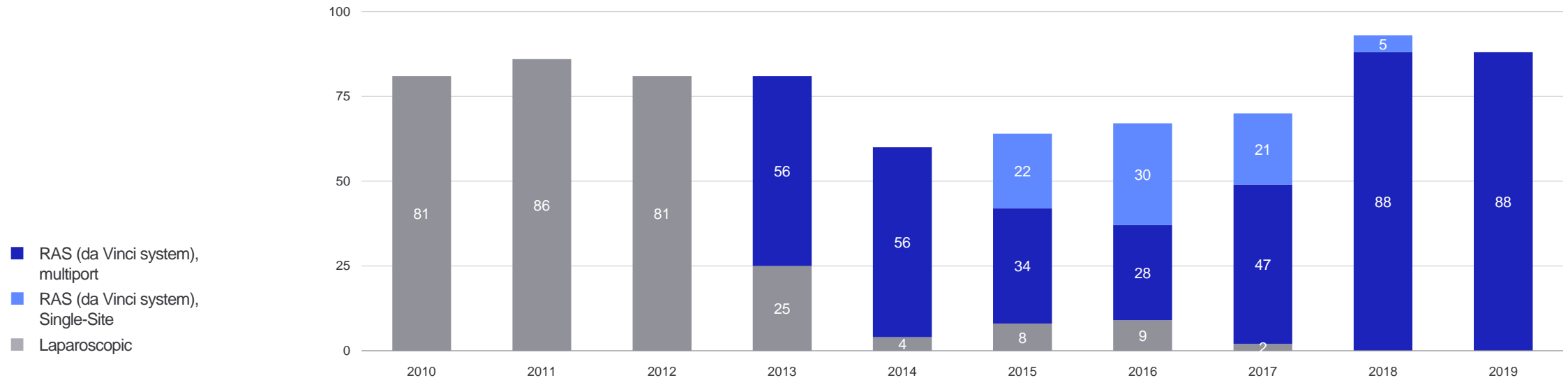
Single-surgeon unpublished experience

Dr. Dhir's comparison of surgical modality

Dr. Nisha Dhir
Princeton Surgical Associates
Princeton, NJ



Modality mix

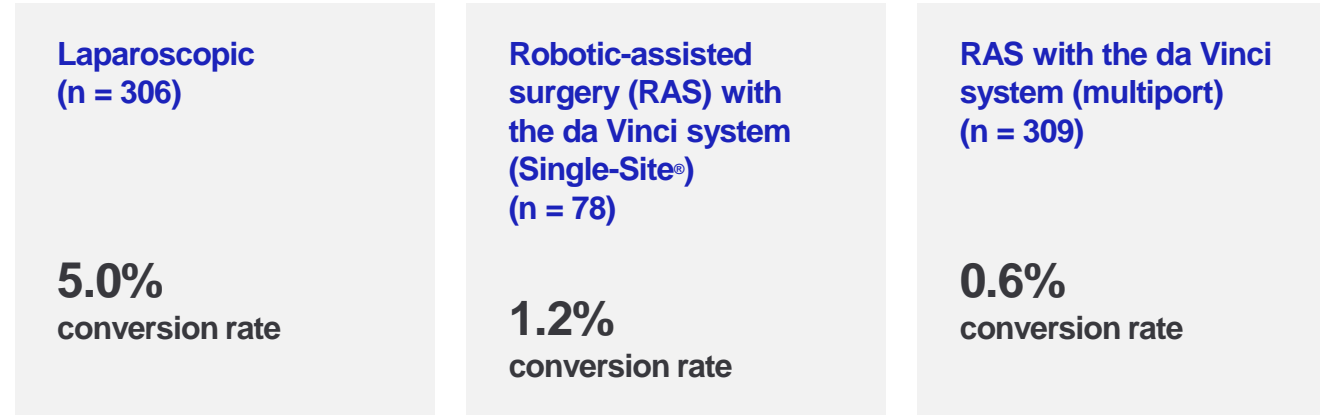


Dr. Nisha Dhir provided data for laparoscopic cases and robotic-assisted (da Vinci system) cases (multiport and Single-Site modalities).

Single-surgeon unpublished experience

Dr. Dhir's conversion rates across modality, January 2010–December 2018

Dr. Nisha Dhir
Princeton Surgical Associates
Princeton, NJ

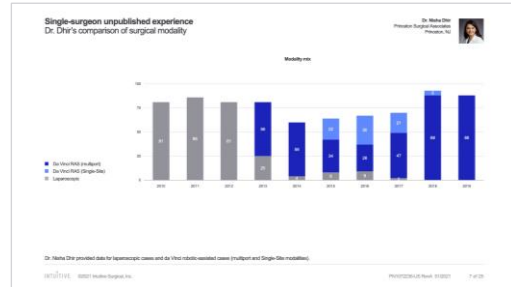


Dr. Nisha Dhir provided data for laparoscopic cholecystectomy cases and robotic-assisted (da Vinci system) cholecystectomy cases (multiport and Single-Site modalities) from 01/2010 - 12/2018.

One study found comparable conversion rates between multiport robotic-assisted surgery (da Vinci system) and laparoscopic surgery. Maeso, S., et al. (2010). "Efficacy of the da Vinci surgical system in abdominal surgery compared with that of laparoscopy: a systematic review and meta-analysis." *Annals of Surgery* 252(2): 254-262.

Single-surgeon unpublished experience

Modality mix and conversion rates - Dr. Dhir's cholecystectomies using da Vinci systems



Modality	n	Conversion rate
Laparoscopic	306	5.0%
Da Vinci robotic-assisted surgery (RAS) (Single-Site)	78	1.2%
Da Vinci RAS (multiport)	309	0.6%

Study design

The surgeon provided data for laparoscopic cases and robotic-assisted cases with a da Vinci surgical system (multiport and Single-Site modalities).

Patient population

Surgeon's patients who had minimally invasive cholecystectomies (01/2010–12/2018)

Outcomes measured / evaluated

- Surgeon provided aggregate data for the outcomes
- Conversions
- Other outcomes (transfusion and/or estimated blood loss, operative time, length of hospital stay, in-hospital complications, readmission rate, reoperation rate, 30-day perioperative mortality, bile leak, and common bile duct injury) were not provided by the surgeon.

Results/conclusions

- Laparoscopic (n = 306): 5.0%
- RAS (da Vinci system, Single-Site, n = 78): 1.2%
- RAS (da Vinci system, multiport, n = 309): 0.6%

Study limitations

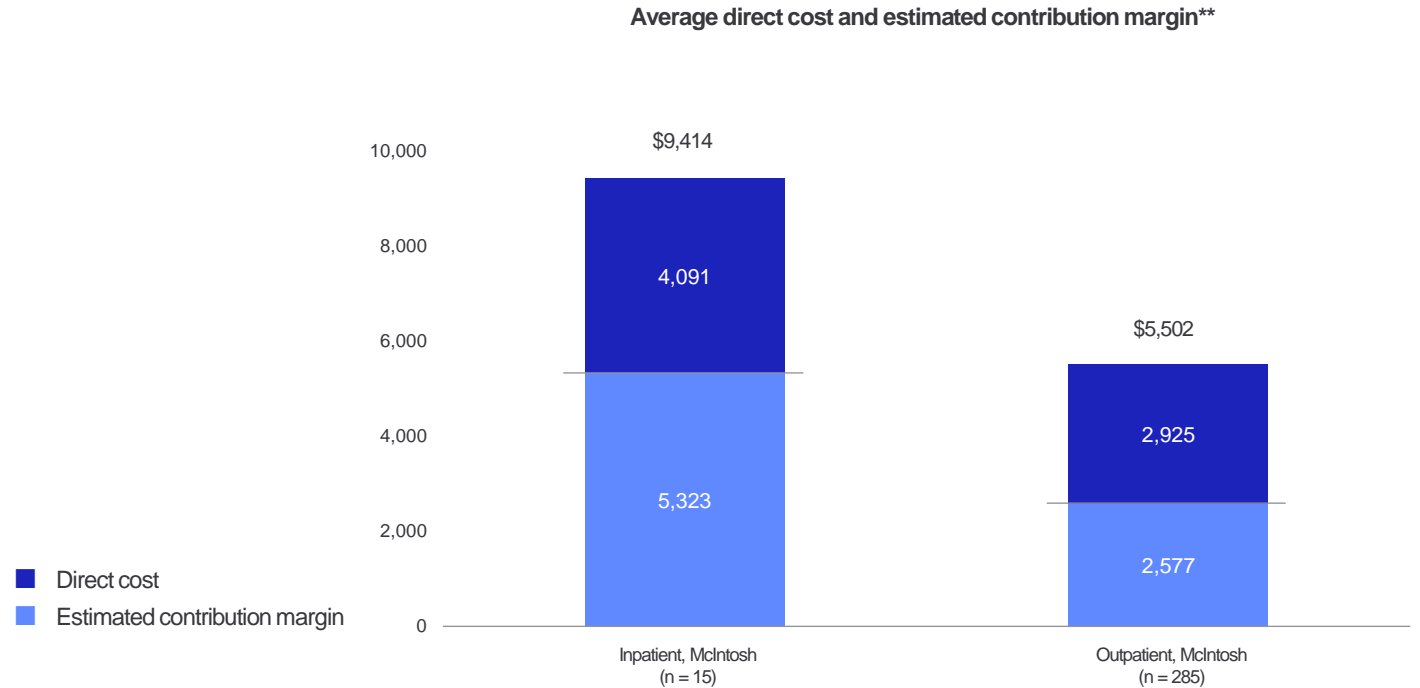
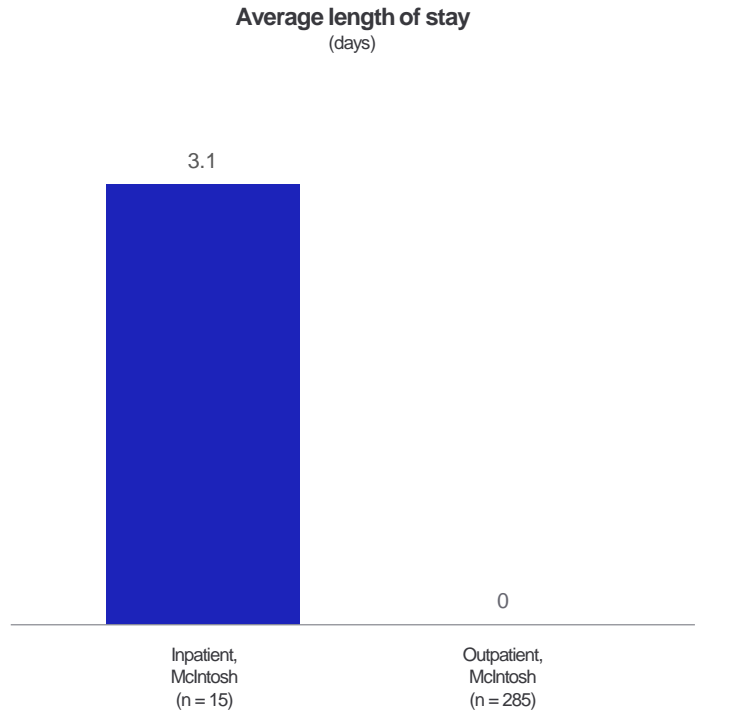
Data presented reflect a single-surgeon experience (data is not collected under formalized study, DATA IS NOT PEER REVIEWED AND NOT PUBLISHED) that may or may not be reproducible and is not generalizable. This data comparison is not case-matched for patient complexity and/or disease status and may not be comparable across these surgical modalities. As such, this data presentation should be considered as informational only and is not conclusive. Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Dr. Nisha Dhir provided data for laparoscopic cholecystectomy cases and robotic-assisted (da Vinci system) cholecystectomy cases (multiport and Single-Site modalities) from 01/2010–12/2018.

Single-surgeon unpublished experience

Dr. McIntosh's robotic-assisted cholecystectomy inpatient data compared to outpatient data

Dr. Bruce McIntosh
Rochester Hills, MI



* Direct cost is a general estimate.

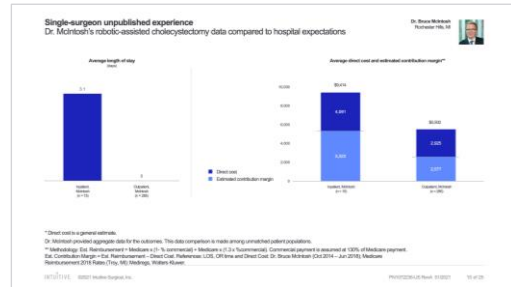
Dr. McIntosh provided aggregate data for the outcomes. This data comparison is made among unmatched patient populations.

** Methodology: Est. Reimbursement = Medicare x (1 - % commercial) + Medicare x (1.3 x %commercial). Commercial payment is assumed at 130% of Medicare payment.

Est. Contribution Margin = Est. Reimbursement – Direct Cost. References: LOS, OR time and Direct Cost: Dr. Bruce McIntosh (Oct 2014 – Jun 2018); Medicare Reimbursement 2018 Rates (Troy, MI): Mediregs, Wolters Kluwer.

Single-surgeon unpublished experience

Clinical outcomes and estimated contribution margins: Dr. McIntosh's cholecystectomies with the da Vinci system



Study design

The surgeon provided data for robotic-assisted cases with a da Vinci surgical system.

Patient population

Surgeon's patients who had robotic-assisted cholecystectomies (10/2014–06/2018)

Outcomes measured / evaluated

- Dr. McIntosh provided aggregate data for:
 - Operative time
 - Length of hospital stay (LOS), and
 - Estimated contribution margin
- Other outcomes (transfusion and/or estimated blood loss, conversions, in-hospital complications, readmission rate, reoperation rate, 30-day perioperative mortality, bile leak, and common bile duct injury) were not provided by the surgeon.

Results/conclusions

- Aggregate data was provided by the surgeon.
- Operative time (min, mean): inpatient 134, outpatient 83
- LOS (days, mean): inpatient 3.1, outpatient 0
- Estimated contribution margin (USD, mean): inpatient \$4,091, outpatient \$2,925

Cost methodology

Dr. McIntosh provided the cost analysis, including the breakdown of the direct cost and estimated contribution margin.

Estimated reimbursement = Medicare X (1 - % commercial) + Medicare X (1.3 X % commercial) Commercial payment is assumed at 130% of Medicare payment.

Estimated contribution margin = Estimated reimbursement – direct cost

References: LOS, OR time, and direct cost: Dr. Bruce McIntosh (Oct 2014 through Jun 2018); Medicare Reimbursement 2018 Rates (Troy, MI); Mediregs, Wolters Kluwer.

Study limitations

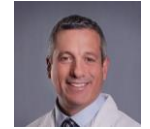
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Dr. Bruce McIntosh provided aggregate data for robotic-assisted cholecystectomy cases performed 10/2014-06/2018.

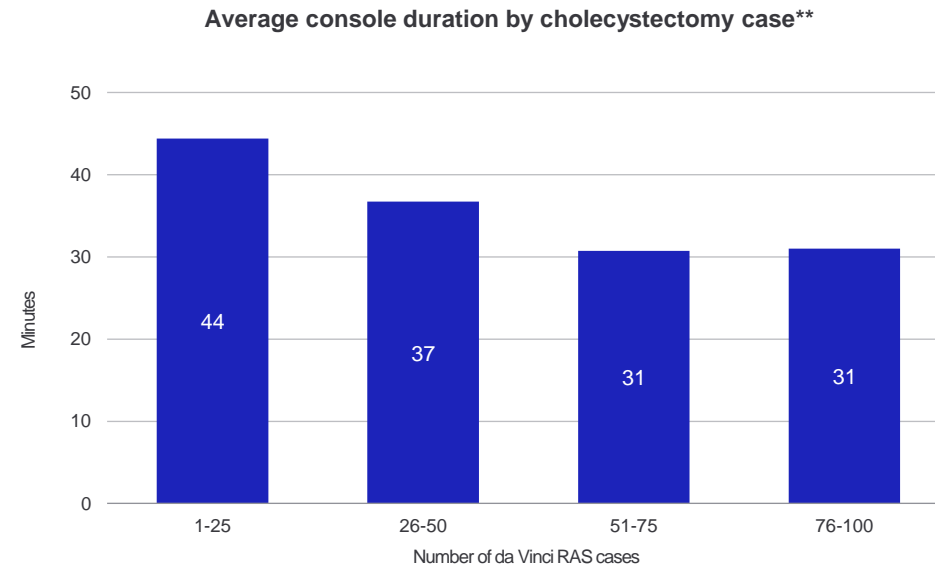
Single-surgeon unpublished experience

Dr. Caravella's conversion rates (compared to published data) and procedure duration data

Dr. Peter Caravella
Valley Hospital Medical Center
Las Vegas, NV



Laparoscopic¹ (Pooled national average; n = 151 studies)	Dr. Caravella, RAS with the da Vinci system (n = 500)
4–6% conversion rate	0.4% conversion rate*



Dr. Peter Caravella provided system log data for robotic-assisted cholecystectomy cases, 05/26/2017–12/31/2019.

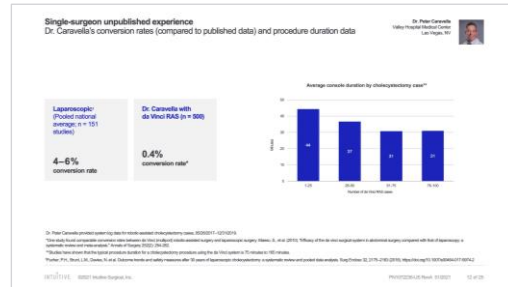
*One study found comparable conversion rates between multiport robotic-assisted surgery (da Vinci system) and laparoscopic surgery. Maeso, S., et al. (2010). "Efficacy of the da Vinci surgical system in abdominal surgery compared with that of laparoscopy: a systematic review and meta-analysis." *Annals of Surgery* 252(2): 254-262.

**Studies have shown that the typical procedure duration for a cholecystectomy procedure using the da Vinci system is 75 minutes to 165 minutes.

¹Pucher, P.H., Brunt, L.M., Davies, N. et al. Outcome trends and safety measures after 30 years of laparoscopic cholecystectomy: a systematic review and pooled data analysis. *Surg Endosc* 32, 2175–2183 (2018). <https://doi.org/10.1007/s00464-017-5974-2>

Single-surgeon unpublished experience

Dr. Caravella's conversion rates (compared to published data) and procedure duration data



Study design

The surgeon provided encounter-level, de-identified patient data for robotic-assisted cholecystectomy cases.

Patient population

Surgeon's patients who had robotic-assisted cholecystectomies (05/26/2017 to 12/31/2019)

Outcomes measured / evaluated

- Dr. Caravella provided encounter-level data to Intuitive for performing the analysis for:
 - Operative time
 - Conversion rate
- Other outcomes (transfusion and/or estimated blood loss, length of hospital stay, in-hospital complications, readmission rate, reoperation rate, 30-day perioperative mortality, bile leak, and common bile duct injury) were not provided by the surgeon.

Results/conclusions

- Analysis was performed by Intuitive using da Vinci system log data provided by the surgeon (n = 500)
- Operative times settled at an average of 31 mins after 500 cases
- Conversion rate was 0.4% for robotic-assisted cholecystectomy, compared to a pooled national range of 4–6%

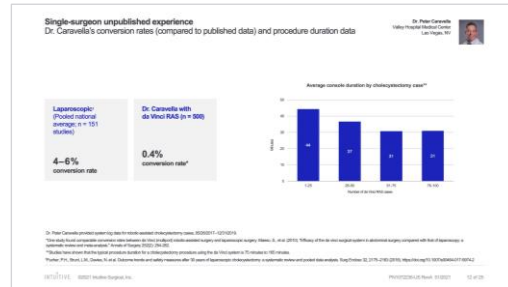
Study limitations

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Dr. Peter Caravella provided system log data for robotic-assisted cholecystectomy cases, 05/26/2017–12/31/2019.

Single-surgeon unpublished experience

Dr. Caravella's cholecystectomies with the da Vinci system versus published results for laparoscopic cholecystectomy (Pucher, et al.)



Study used for comparison

Outcome trends and safety measures after 30 years of laparoscopic cholecystectomy: a systematic review and pooled data analysis.

Study design

Meta-regression analysis of pooled data of laparoscopic procedures through various data sources to assess factors associated with conversion, morbidity and bile duct injury (BDI) rates

Patient population

- One hundred fifty-one (151) studies of laparoscopic procedures involving 505,292 patients were included.
- Outcome data were pooled before meta regression analysis.

Outcomes measured / evaluated

Conversions, morbidity, BDI, and mortality rates were analyzed.

Results / conclusions

- Overall conversion rates were 4.2–6.2%
- Overall BDI rates stood at 0.32–0.52%
- Overall morbidity was at 1.6–5.3%
- Overall mortality was at 0.08–0.14%

Study limitations

- Limited statistical power to identify differences in BDI rates due to relatively low prevalence and/or incidence rates
- Minimal sample sizing to reduce to the risk of selection bias
- Most BDIs were neither reported nor published so the true

rate of BDI is not precisely known.

- Detailed coding is not available (categorization not available, other than 'BDI').

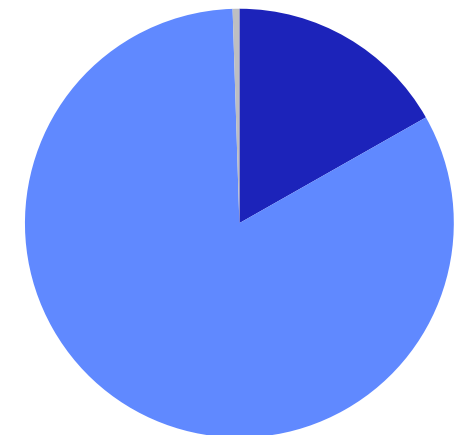
Pucher P, Brunt L, Davies N et al. Outcome trends and safety measures after 30 years of laparoscopic cholecystectomy: a systematic review and pooled data analysis. Surg Endosc. 2018;32(5):2175-2183. doi:10.1007/s00464-017-5974-2

Single-institution unpublished experience

Hackensack Meridian: Financial and operational key performance indicators, FY 2018

	Outpatient			Inpatient		
	Open (n = 2)	Lap (n = 463)	RAS (da Vinci system) (n = 100)	Open (n = 2)	Lap (n = 192)	RAS (da Vinci system) (n = 33)
Average OR time (mean, min)	86	118	128	174	149	163
Average LOS (mean, days)	1.5	1.6	1.2	9.0	5.3	4.8

Overall modality mix (FY 2018)*



- RAS (da Vinci system), n = 133
- Lap n = 655
- Open n = 4

Hackensack Meridian Medical Center provided FY 2018 data for cholecystectomy procedures.

*Includes both inpatient and outpatient modality mix

Single-center unpublished experience

Hackensack Meridian: Financial and operational key performance indicators, FY 2018



Study design

The hospital system provided data for cholecystectomy cases with the da Vinci surgical system, laparoscopy, and open modalities

Patient population

Patients who underwent cholecystectomy cases during Hackensack Meridian's 2018 fiscal year

- RAS (da Vinci system): n = 133
- Laparoscopic: n = 655
- Open: n = 4

Outcomes measured / evaluated

- Length of stay
- Operative times
- Other outcomes (transfusion and/or estimated blood loss, conversion rate, in-hospital complications, readmission rate, reoperation rate, 30-day perioperative mortality, bile leak, and common bile duct injury) were not provided by the hospital system.

Results/conclusions

- Data and the analysis was provided by Hackensack Meridian Medical Center for FY 2018
- Average OR time for RAS was 10 mins higher than laparoscopic for inpatient, and 14 mins for outpatient.
- Average LOS were lower for RAS by 0.4 days for inpatient and by 0.5 days for outpatient compared to laparoscopic

Study limitations

Data presented reflect a single-institution experience (data is not collected under formalized study, DATA IS NOT PEER REVIEWED AND NOT PUBLISHED) that may or may not be reproducible and is not generalizable. This data comparison is not case-matched for patient complexity and/or disease status and may not be comparable across these surgical modalities. As such, this data presentation should be considered as informational only and is not conclusive. Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Hackensack Meridian Medical Center provided FY 2018 data for cholecystectomy procedures.

Single-surgeon unpublished experience

Dr. Vijan's cholecystectomy volume by care setting and clinical outcomes, FY 2017–2018

Dr. Sandeep Vijan
Parkview Medical Center
Pueblo, CO



	Inpatient			Outpatient		
	Open (n = 8)	Lap (n = 185)	RAS (da Vinci system) (n = 26)	Open (n = 1)	Lap (n = 397)	RAS (da Vinci system) (n = 116)
OR time (median, min)	133	88	86*	67	76	82*
LOS (median, days)	12.0	3.0	3.0	1.0	1.0	1.0

Dr. Sandeep Vijan provided aggregate data for cholecystectomies performed during FY 2017–2018

*Studies have shown that the typical procedure duration for a cholecystectomy procedure using the da Vinci system is 75 minutes to 165 minutes.

Single-surgeon unpublished experience

Dr. Vijan's cholecystectomy volume by care setting and clinical outcomes, FY 2017–2018

Dr. Sandeep Vijan
Parkview Medical Center
Pueblo, CO



Overall		
	Laparoscopic (n = 560)	Robotic-assisted (n = 142)
Conversions, n (%)	9 (1.6)	0 (0)*
Bile leaks, n (%)	10 (1.9)	0 (0)**

Dr. Sandeep Vijan provided aggregate data for cholecystectomies performed during FY 2017–2018

*One study found comparable conversion rates between between multiport robotic-assisted surgery (da Vinci system) and laparoscopic surgery. Maeso, S., et al. (2010). "Efficacy of the da Vinci surgical system in abdominal surgery compared with that of laparoscopy: a systematic review and meta-analysis." *Annals of Surgery* 252(2): 254-262.

**One study found comparable bile leak rates between between multiport robotic-assisted surgery (da Vinci system) and laparoscopic surgery. Strosberg, D. S., et al. (2016). "A retrospective comparison of robotic cholecystectomy versus laparoscopic cholecystectomy: operative outcomes and cost analysis." *Surgical Endoscopy*.

Single-surgeon unpublished experience

Dr. Vijan's cholecystectomy volume by care setting and clinical outcomes, FY 2017–2018

Single-surgeon unpublished experience
Cholecystectomy volume by care setting and clinical outcomes, FY 2017–2018

	Inpatient			Outpatient		
	Open (n=14)	Lap. (n=76)	da Vinci® (n=26)	Open (n=1)	Lap. (n=11)	da Vinci® (n=10)
OR time (mins)	133	86	87	97	76	87
LOS (median, IQR)	12.3	3.0	3.3	1.0	1.0	1.0

Dr. Sandeep Vijan provided aggregate data for cholecystectomies performed during FY 2017–2018. This data is not peer-reviewed and is for informational purposes only. It is not intended to be used as a basis for clinical decisions. © 2021 Intuitive Surgical, Inc. All rights reserved. This document is confidential and its use is restricted to the intended recipient. For more information, please contact your account manager. Intuitive Surgical, Inc. is not responsible for any errors or omissions in this document. All trademarks are the property of their respective owners. Intuitive Surgical, Inc. is not responsible for any errors or omissions in this document. All trademarks are the property of their respective owners. Intuitive Surgical, Inc. is not responsible for any errors or omissions in this document. All trademarks are the property of their respective owners.

Study design

The surgeon provided data for cholecystectomies cases with the da Vinci surgical system, laparoscopy, and open modalities.

Patient population

- Surgeon’s patients who had cholecystectomy procedures within the fiscal years 2017–2018.
- N = 733

Outcomes measured/evaluated

Dr. Vijan provided aggregate data for:

- Conversions
- Bile leaks
- Length of stay
- Operative time
- Other outcomes (transfusion and/or estimated blood loss, in-hospital complications, readmission rate, reoperation rate, 30-day perioperative mortality, and common bile duct injury) were not provided by the surgeon.

Results/conclusions

- In the outpatient group, median operative time for cholecystectomy with the da Vinci system was higher (82 mins) compared to laparoscopic cholecystectomy (76 mins).

- In the inpatient group, median operative time for cholecystectomy with the da Vinci system was lower (86 mins) compared to laparoscopic cholecystectomy (133 mins).
- In the inpatient group, the median length of stay was higher in the open group (12 days) versus the robotic-assisted group (3 days).
- Cholecystectomies with the da Vinci system resulted in no conversions or bile leaks compared to laparoscopic cholecystectomy (1.6% conversion rate, 1.9% bile leak rate).

Study limitations

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Dr. Sandeep Vijan provided aggregate data for cholecystectomies performed during FY 2017–2018

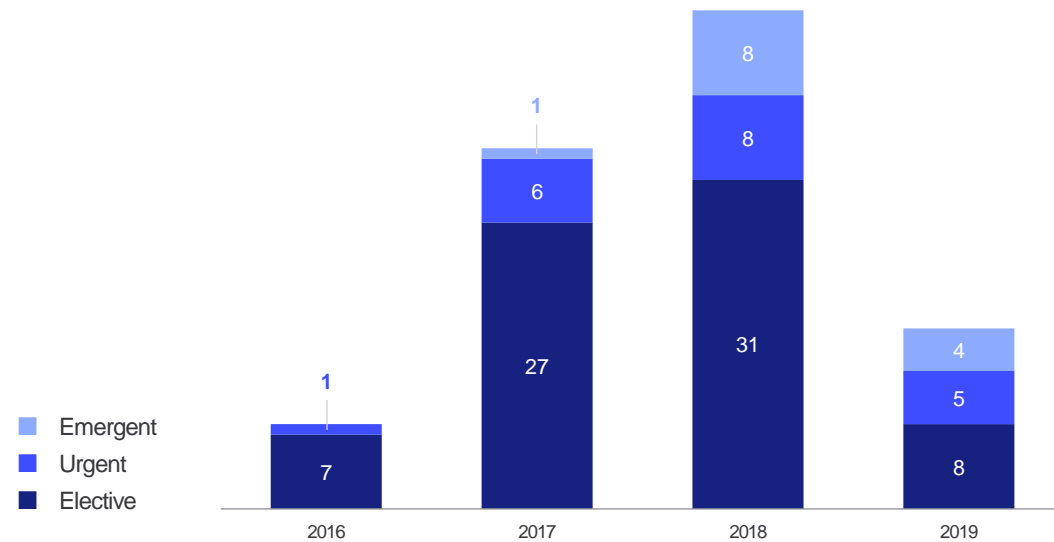
Single-surgeon unpublished experience

Dr. Toomari's robotic-assisted cholecystectomy volume, January 2016–April 2019

Dr. Nojan Toomari
Tarzana Medical Center
Tarzana, CA



Da Vinci system case volume per year, by case status

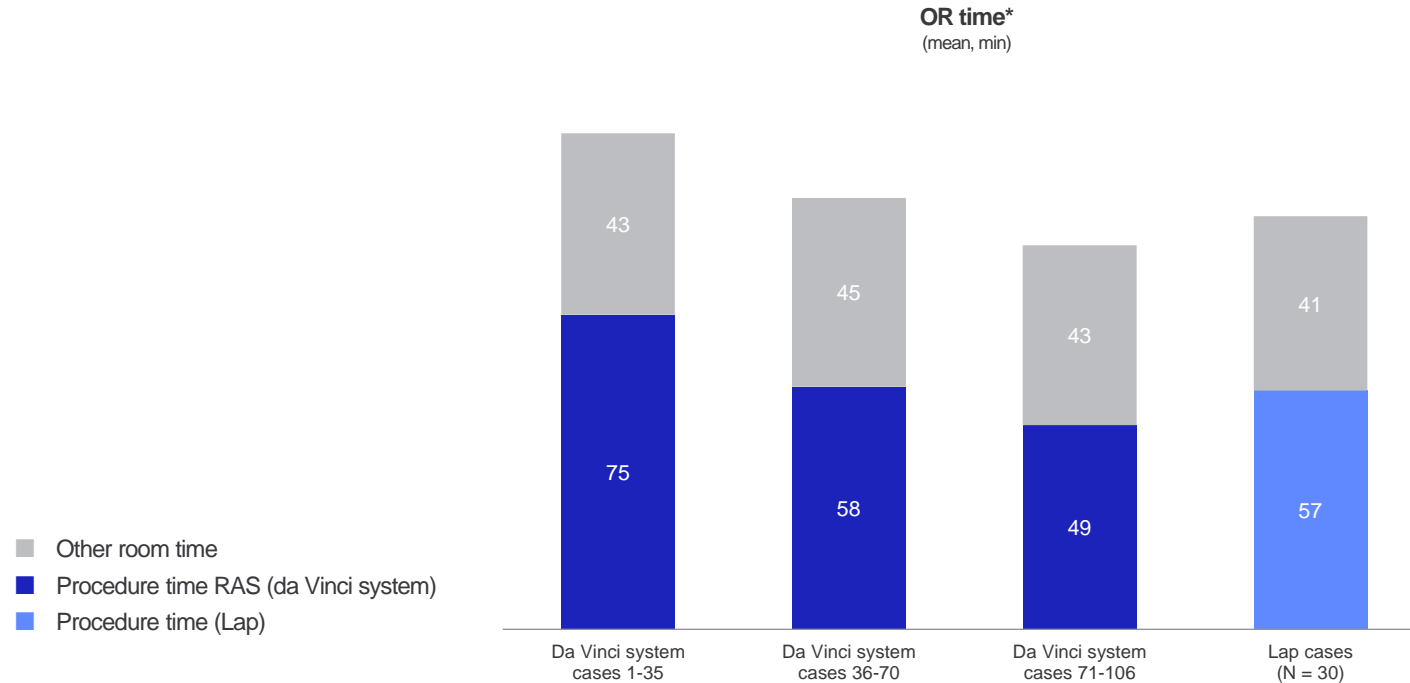


Dr. Toomari provided data for procedures performed with the da Vinci surgical system from 01/2016 through 04/2019.

Single-surgeon unpublished experience

Dr. Toomari's procedure times for robotic-assisted cholecystectomy

Dr. Nojan Toomari
 Tarzana Medical Center
 Tarzana, CA



Dr. Toomari's cholecystectomy procedure times with the da Vinci system have decreased by 35% since his first 35 cases†

Dr. Toomari provided procedure time data for RAS (da Vinci system) and laparoscopic procedures for 01/2016–04/2019.

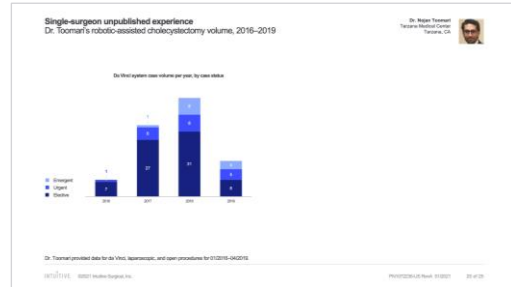
*OR time is defined here as wheels-in to wheels-out time, which comprises procedure (i.e., skin-to-skin) time and other room time.

†(75 minutes - 49 minutes)/75 minutes X 100 = 34.7%

Other studies have shown that the typical procedure duration for a cholecystectomy procedure using the da Vinci system is 75 minutes to 165 minutes.

Single-surgeon unpublished experience

Dr. Toomari's robotic-assisted cholecystectomy volume, and OR times for robotic-assisted cholecystectomy



Study design

The surgeon provided data for robotic-assisted cases with the da Vinci surgical system.

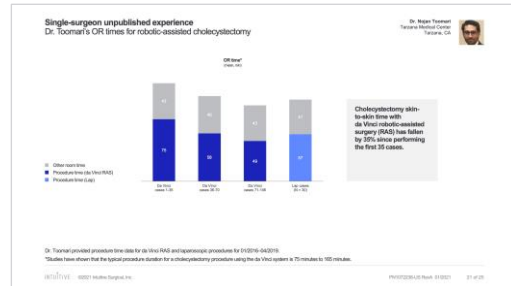
Patient population

Surgeon's patients who had laparoscopic or robotic-assisted cholecystectomy procedures between 01/2016–04/2019

Outcomes measured / evaluated

Dr. Toomari provided aggregate data for:

- OR times segmented into 35-case blocks
- Other outcomes (transfusion and/or estimated blood loss, length of stay, conversions, in-hospital complications, readmission rate, reoperation rate, 30-day perioperative mortality, bile leak, and common bile duct injury) were not provided by the surgeon.



Results/conclusions

- Analysis was performed by Intuitive from the aggregate data provided by the surgeon.
- Dr. Toomari's mean OR time for laparoscopic cholecystectomy was 57 min (n = 30)
- Dr. Toomari's mean OR times for robotic-assisted cholecystectomies (n = 106) was 75 min for cases 1–35, 58 min for cases 36–70, and 49 min for cases 71–106.
- Cholecystectomy OR time with the da Vinci system decreased 35% since his first 35 cases.

Study limitations

Data presented reflect a single-surgeon experience (data is not collected under formalized study, DATA IS NOT PEER REVIEWED AND NOT PUBLISHED) that may or may not be reproducible and is not generalizable. This data comparison is not case-matched for patient complexity and/or disease status and may not be comparable across these surgical modalities. As such, this data presentation should be considered as informational only and is not conclusive. Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

Dr Toomari provided aggregate data for laparoscopic and robotic-assisted cholecystectomy procedures performed from 01/2016 through 04/2019.

Additional outcomes for robotic-assisted cholecystectomy as compared to laparoscopic cholecystectomy¹

Variable	RC (N = 140)	LC (N = 97)	P Value*
Conversion to open, N (%)	1 (0.7)	7 (7.2)	< .01
Blood loss (mL)	10 (2–200)	10 (5–600)	.12
Perioperative transfusion, N (%)	0 (0.0)	1 (1.0)	.40
Length of surgery (min)	74.5 (47–293)	56 (35–244)	< .01
Hospital stay (days)	0 (0–4)	0 (0–8)	.09
30-day readmission, N (%)	5 (3.6)	4 (4.1)	1.00
Bile duct injury, N (%)	0 (0)	0 (0)	1.00
Bile leak, N (%)	3 (2.1)	1 (1.0)	.65
Reoperation, N (%)	2 (1.4)	1 (1.0)	1.00

*Calculated with Wilcoxon rank-sum test or Fisher's exact test. Bold values are statistically significant difference with alpha of 0.05.

¹Strosberg DS, Nguyen MC, Muscarella P 2nd, Narula VK. A retrospective comparison of robotic cholecystectomy versus laparoscopic cholecystectomy: operative outcomes and cost analysis. Surg Endosc. 2017;31(3):1436-1441. doi:10.1007/s00464-016-5134-0

Important safety information

Surgical risks for cholecystectomy include: common bile duct injury; bile leak; pancreatitis, retained common bile duct stones.

Serious complications may occur in any surgery, including surgery with the da Vinci surgical system, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain.

Risks specific to minimally invasive surgery, including surgery with the da Vinci surgical system, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments.

For Important Safety Information, indications for use, risks, full cautions and warnings, please also refer to <http://www.intuitive.com/safety>.

Individual outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience.

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