Mathur M, Vaidya P, Yankovsky A, Kreaden U.S Intuitive Surgical, Sunnyvale, CA, USA

INTRODUCTION

Robot-assisted surgery using da Vinci surgical system (dV-RAS) is seeing an increase in use for benign gynecologic conditions such as uterine fibroids, ovarian cysts, endometriosis, pelvic organ prolapse, and uterine bleeding. There is a need for a comprehensive summary of current publications to assess the value dV-RAS compared to laparoscopic (Lap) or traditional open approaches.

AIM

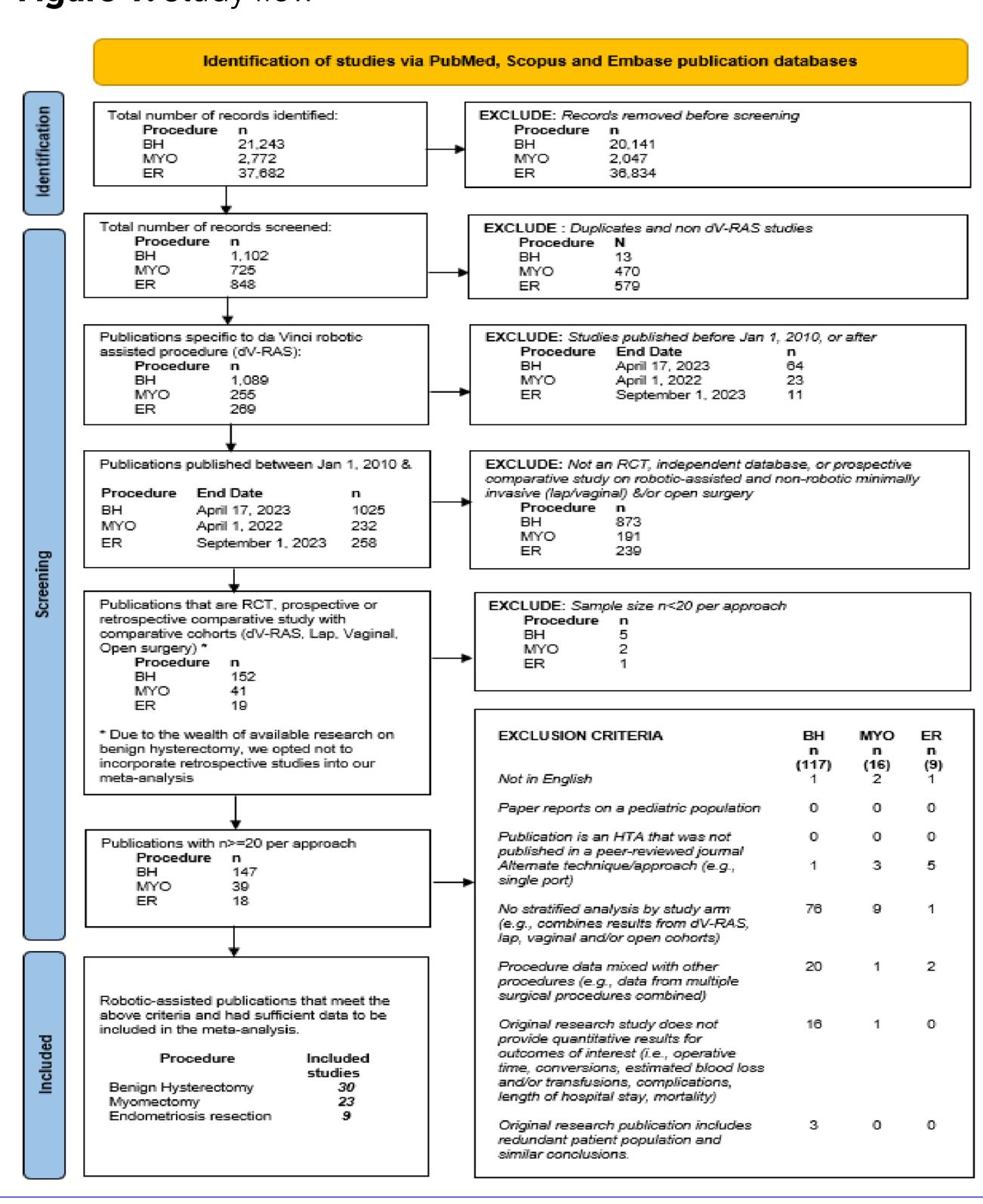
To review and synthesize the evidence across three benign gynecologic procedures to understand the results of common perioperative clinical outcomes and value of dV-RAS, presented as a meta-analysis.

METHODS

A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guided literature review and R software based meta-analysis assessed studies where dV-RAS was compared to Lap or open approach in benign hysterectomy (BH), myomectomy (MYO), and endometriosis resection (ER).

A PubMed, Embase, and Scopus search spanning a 12-year period was performed for each procedure and screened for eligibility based on title, keywords and abstracts.

Figure 1. Study flow



RESULTS

The search identified 30 publications on BH, 22 on MYO, and 9 on ER.

Table 1. Comparative analysis by surgical modality for benign gynecological procedures

| Outcome | Comparison | Studies | dV-RAS N | Lap/Open N | Effect size | p-value of Effect size | Heterogeneity | Model | Conclusion |
|----------------------------------|----------------|------------------------|-------------|---------------|-------------------------------|---------------------------|-----------------------------|--------|--------------------|
| Operative time (min) | dV-RAS vs LAP | BH(12), MYO(14), ER(8) | 29534 | 93321 | MD: 34.10 [21.72; 46.49] | p<0.01 | p=0; I ² =99% | Random | Favors LAP |
| | dV-RAS vs Open | BH(4), MYO(13) | 22959 | 148115 | MD: 62.56 [42.93, 82.19] | p<0.01 | p<0.01; I ² =99% | Random | Favors Open |
| Conversion to open (%) | dV-RAS vs LAP | BH(14), MYO(10), ER(6) | 90056 | 178787 | OR: 0.35 [0.24, 0.50] | p<0.01 | p<0.01; I ² =93% | Random | Favors RAS |
| | dV-RAS vs Open | | | | Not applicable | | | | |
| Estimated blood loss (ml) | dV-RAS vs LAP | BH(6), MYO(13), ER(6) | 3776 | 3667 | MD: -11.63 [-33.64; 10.38] | p=0.30 | p<0.01; I ² =94% | Random | No difference |
| | dV-RAS vs Open | BH(4), MYO(13) | 2236 | 9268 | MD: -102.90 [-163.62, -42.18] | p<0.01 | p<0.01; I ² =97% | Random | Favors RAS |
| Blood transfusions (%) | dV-RAS vs LAP | BH(11), MYO(12), ER(2) | 49207 | 138099 | OR: 0.79 [0.69, 0.91] | p<0.01 | p=0.09; I ² =31% | Fixed | Favors RAS |
| | dV-RAS vs Open | BH(5), MYO(10) | 29468 | 155600 | OR: 0.28 [0.20, 0.38] | p<0.01 | p<0.01; I ² =68% | Random | Favors RAS |
| Post-op complications 30-day (%) | dV-RAS vs LAP | BH(13), MYO(11), ER(5) | 126225 | 196507 | OR: 0.87 [0.76, 0.99] | p=0.04 | p<0.01; I ² =88% | Random | Favors RAS |
| | dV-RAS vs Open | BH(7), MYO(9) | 106198 | 834039 | OR: 0.47 [0.38, 0.59] | p<0.01 | p<0.01; I ² =97% | Random | Favors RAS |
| Length of hospital stay (days) | dV-RAS vs LAP | BH(13), MYO(11), ER(5) | 44510 | 112699 | MD: -0.08 [-0.23; 0.07] | p=0.29 | p<0.01; I ² =93% | Random | No difference |
| | dV-RAS vs Open | BH(6), MYO(13) | 32392 | 164884 | MD: -1.48 [-1.77; -1.19] | p<0.01 | p=0; I ² =99% | Random | Favors RAS |
| Readmissions 30-day (%) | dV-RAS vs LAP | BH(6), MYO(0), ER(2) | 22555 | 36855 | OR: 0.90 [0.82; 0.99] | p=0.03 | p=0.07; I ² =48% | Fixed | Favors RAS |
| | dV-RAS vs Open | BH(4), MYO(2) | 22516 | 170233 | OR: 0.94 [0.65; 1.34] | p=0.73 | p<0.01; I ² =89% | Random | No difference |
| Reoperations 30-day (%) | dV-RAS vs LAP | BH(5), MYO(3), ER(3) | 14804 | 24635 | OR: 0.92 [0.66; 1.28] | p=0.63 | p=0.86; I ² =0% | Fixed | No difference |
| | dV-RAS vs Open | BH(3), MYO(1) | 14561 | 22212 | OR: 0.45 [0.18; 1.14] | p=0.09 | p<0.01; I ² =85% | Random | No difference |

Figure 2. Detailed Forest-plot for Conversion to open surgery

| Study or | dV-RAS | Lap | Lap CONV | | Odds Ratio | Odds Ratio | | |
|--|--------------------|-------|-------------|-------------------------|------------|-------------------------|--|--|
| Subgroup | Events | Total | Events | Total | Weight | MH, Random, 95% C | MH, Random, 95% CI | |
| Procedure = Myomecto | my | | | | | | | |
| Aendekerk 2019 | 4 | 51 | 8 | 84 | 4.8% | 0.8085 [0.2307; 2.8336 | S] ——— | |
| Chen 2018 | 1 | 26 | 1 | 52 | 1.4% | 2.0400 [0.1225; 33.9796 | 5] | |
| Gobern 2013 | 3 | 66 | 6 | 73 | 4.0% | 0.5317 [0.1275; 2.2175 | 5] | |
| Hsiao 2013 | 0 | 20 | 2 | 22 | 1.2% | 0.2000 [0.0090; 4.4283 | <u> </u> | |
| Jansen 2018 | 1 | 163 | 6 | 185 | 2.3% | 0.1842 [0.0219; 1.5460 | oj — • — — — — — — — — — — — — — — — — — | |
| MacKoul 2018 | 10 | 156 | 27 | 163 | 7.6% | 0.3450 [0.1610; 0.7394 | <u> </u> | |
| Morales 2021 | 1 | 24 | 2 | 24 | 1.8% | 0.4783 [0.0404; 5.6576 | <u> </u> | |
| Ozbash 2021 | 0 | 66 | 0 | 88 | 0.0% | - | | |
| Pluchino 2013 | 0 | 43 | 2 | 43 | 1.2% | 0.1908 [0.0089; 4.0939 | 91 | |
| Sheu 2019 | 0 | 93 | 0 | 110 | | • | | |
| Total (95% CI) | 20 | 708 | 54 | | | 0.4285 [0.2524; 0.7274 | 11 | |
| Heterogeneity: Tau ² = 0; Chi | | | | | | | | |
| Procedure = Benign Hy | sterectom | ıy | | | | | | |
| Billfeldt 2018 | 16 | 1015 | 154 | 1539 | 9.3% | 0.1463 [0.0872; 0.2456 | S] —— | |
| Brunes 2021 | 26 | 1784 | | 2344 | | 0.1511 [0.1000; 0.2282 | - | |
| Deimling 2017 | 0 | 72 | 0 | 72 | 0.0% | - | | |
| Elessawy 2020 | 0 | 56 | 0 | 99 | 0.0% | | | |
| Lim 2016 Multicenter | 2 | | | 11952 | | 0.9448 [0.2093; 4.2652 | 21 | |
| Lim 2016 Risk | 71 | 4528 | | 2464 | | 0.1765 [0.1341; 0.2323 | - | |
| Lonnerfors 2015 | 0 | 61 | 2 | 36 | | 0.1122 [0.0052; 2.4045 | - | |
| Luciano 2016 | 514 | 20781 | 5585 | 78148 | | 0.3295 [0.3006; 0.3611 | - | |
| Martinez-Maestre 2014 | 0 | 51 | 0 | 54 | 0.0% | - | | |
| Ngan 2018 | 284 | 10677 | 883 | 33088 | | 0.9962 [0.8699; 1.1407 | 7] ↓ | |
| Paraiso 2013 | 0 | 26 | | 26 | | 0.3208 [0.0125; 8.2431 | - I | |
| Pellegrino 2017 | 0 | 64 | | 130 | | 0.2179 [0.0116; 4.1101 | | |
| Sarlos 2012 | 0 | 47 | 0 | 48 | 0.0% | - | | |
| Shah 2022 | 906 | 47673 | _ | | | 0.3265 [0.3025; 0.3524 | .1 🙃 | |
| Total (95% CI) | | 89135 | | | | 0.2966 [0.1936; 0.4544 | | |
| Heterogeneity: Tau ² = 0.2957 | | | | | | | | |
| Procedure = Endometri | osis Rese | ction | | | | | | |
| Ferrier 2022 | 2 | 61 | 1 | 61 | 1.8% | 2.0339 [0.1796; 23.038; | 3] | |
| LeGac 2020 | 0 | 23 | 0 | 25 | 0.0% | | | |
| Nezhat 2010 | 0 | 40 | 0 | 38 | 0.0% | | | |
| Nezhat 2014 | 0 | 32 | 0 | 86 | 0.0% | | | |
| Raimondo 2021 | 1 | 22 | 0 | 22 | 1.1% | 3.1395 [0.1212; 81.353 | 9] | |
| Soto 2017 | 0 | 35 | 1 | 38 | | 0.3521 [0.0139; 8.9311 | _ | |
| Total (95% CI) | 3 | 213 | 2 | 270 | | 1.4299 [0.2699; 7.5743 | - | |
| Heterogeneity: Tau ² = 0; Chi | $^2 = 1.03, df = $ | | | | | | | |
| Total (95% CI) | 1842 | 90056 | 9779 | 178787 | 100.0% | 0.3481 [0.2438; 0.4971 | | |
| Heterogeneity: Tau ² = 0.2858 Test for overall effect: Z = -5. | - | - | = 20 (P < 0 | 0.01); I ² = | 93% | | 0.01 0.1 1 10 10 | |
| | _ | • | 2 (P = 0.15 | | | | 3.3. 3.1 1 10 10 | |

RESULTS

Compared to Lap surgery the evidence for dV-RAS benign gynecologic procedures demonstrates:

- 65% lower likelihood of a conversion to open surgery with dV-RAS
- 21% lower likelihood of receiving a blood transfusion with dV-RAS
- 13% lower likelihood of experiencing a complication with dV-RAS
- Significantly longer operative time with dV-RAS by an average of 34 minutes
- Comparable length of hospital stay, estimated blood loss, postoperative readmission and reoperation within 30-days of surgery

Compared to Open surgery the evidence for dV-RAS benign gynecologic procedures demonstrates:

- 72% lower likelihood of receiving a blood transfusion with dV-RAS
- 53% lower likelihood of experiencing a complication with dV-RAS
- 10% lower likelihood of a 30-day readmission with dV-RAS
- Significantly shorter hospital length of stay by an average of
 1.5 days with dV-RAS
- Significantly less estimated blood loss with dV-RAS by an average of 103 ml
- Significantly longer operative time with dV-RAS by an average of 62 minutes
- Comparable rate of reoperations within 30-days of surgery

CONCLUSIONS

- results in lower conversion rates, fewer blood transfusions and fewer postoperative complications when compared to Lap.
- > dv-RAS for benign gynecologic surgery results in fewer blood transfusions, less blood loss, shorter hospital stay, fewer postoperative complications and a reduction in readmissions compared to Open surgery.
- The increase in minimally invasive surgery (MIS) is supported by the results of this meta-analysis.
- This holistic approach to summarizing the evidence can help regulators and decision makers in evaluating dv-RAS for benign gynecologic procedures.

CONTACT

Name: Mansi Mathur

Email: <u>mansi.mathur@intusurg.com</u>