SHTG Assessment 03-21
January 2021

Review of recently published evidence on the relationship between the volume of robotic-assisted surgery (RAS) performed and the outcomes achieved

What were we asked to look at?

The National Planning Robotic Review Group requested an evidence summary on the impact of the number of robotic-assisted procedures (gynaecological, colorectal, urological) per treatment centre/surgeon on the outcomes achieved, and any related evidence on the learning curves for these procedures.

Why is this important?

As robotic-assisted surgery is used more frequently and across a growing number of indications in NHSScotland, it is essential that surgeons and hospitals undertake sufficient numbers of procedures to ensure optimal effectiveness, safety and cost effectiveness.

What was our approach?

A rapid review was conducted to identify the best available recently published evidence to address this topic.

What next?

This report was used to inform discussions by the National Planning Robotic Review Group around the provision of robotic services within Scotland.

Key findings

- Only a small number of studies were identified, most of them with methodological issues affecting their validity. Definitions of high and low volumes differ across studies and make comparisons between studies and indications difficult.
- The limited evidence is strongest for urological procedures and shows positive associations between higher volume centres and better outcomes.
- Gynaecological RAS – no systematic reviews identified; recent observational studies primarily considered minimally invasive surgery in general and did not separate out results for RAS.
- Colorectal RAS – no systematic reviews identified; several recent observational studies primarily considered minimally invasive surgery in general and did not separate out results for RAS. One retrospective observational study (based upon 957 procedures) reported improvements in operative times, conversion rates and length of stay for high versus low volume surgeons.
- Urological RAS (radical prostatectomy) – one systematic review that primarily reported collated outcomes for all type of surgery, concluded that higher volume surgical centres have better outcomes and this relationship is still seen when considering RAS alone. Two large retrospective observational studies from the United States reported improvements in a number of outcomes with higher volume hospitals, but used different volume definitions complicating comparisons. Two cost analyses (United States and Australia) showed reduced costs at higher volume centres.
- Urological RAS (radical cystectomy) – one systematic review was identified which included 49 studies but considered all surgical approaches. Only one included primary study reported RAS outcomes (based upon data gathered back to 2011) and considered a comparison of the first one hundred with the second hundred patients. Other than a shorter operative time for the latter group, no differences in outcomes were observed.
- Urological RAS (partial nephrectomy) – two retrospective observational studies reported improvements in various outcomes with increasing hospital volume. One of the studies also considered surgical volume and again showed improvements in outcomes with increasing volume. A multivariate analysis however found that when adjusting for other variables hospital volume but not surgeon volume was associated with achieving the Trifecta outcome.
- Learning curves – one recent systematic review was identified which included 49 studies. The review authors present the number of procedures necessary to

'overcome the learning curve' for various clinical and oncology specific outcomes. They note the generally poor methodological quality of much of the evidence and the need to interpret the results with caution.

Contents

Literature search

A systematic search of the secondary literature was carried out on 28th September 2020 to identify systematic reviews, health technology assessments and other evidence based reports.

The primary literature was systematically searched on the 28th September 2020 using the following databases: Medline, Medline in process, Cochrane, Embase and Science Direct.

Results in both cases were limited to studies published between 1st January 2016 and the date of the search. Only studies with an English language abstract were included. No restrictions by study design were applied.

Concepts used in all searches included: robotic/robot-assisted surgery/surgeries/surgical, computer assisted surgery/surgeries/surgical, da vinci, gynaecological and oncological terms, colorectal terms, urological terms, laparoscopic terms. A full list of resources searched and terms used are available on request.

Introduction

In January 2019 the NHSS National Planning Board commissioned a short life working group to review RAS in Scotland, with the purpose of exploring current usage and scope, and developing wider evidence of future use of robotic surgery. The review reported to the National Planning Board in November 2019 and the creation of a National Strategic Framework for RAS in NHSScotland was supported. The draft framework was considered and approved by the National Planning Board on 21st February 2020.

The objectives of the framework are:

- Establish agreed surgical expansion areas for RAS across Scotland, agree phases of expansion to increase RAS minimally invasive surgery and reduce inequalities of access to RAS and the enhanced patient outcomes;
- Provision of a training model for Scotland and ensure sustainability of a multidisciplinary workforce in world class centres of excellence, that will attract surgeons to train in/come to/stay in Scotland;
- Establish agreed coding and datasets to monitor RAS and measure success;
- Support innovation and relationships with academia and industry to ensure ongoing development of evidence;
- Establish a finance framework and rolling procurement model for expansion and maintenance of new and existing RAS systems.

As part of the RAS Framework implementation, a data subgroup has been created. To inform their work, this group has requested a summary of the evidence on the impact of the volume of RAS procedures (per surgeon/and per treatment centre) on clinical outcomes, and also related information on the learning curves for surgeons.

Health technology description

The technology for RAS comprises a surgeon console, computerised control system, and patient-side cart that houses the robotic arms which hold the dual telescope and surgical instruments. The surgeon operates the robotic arms by remote control from the console while viewing the magnified 3D surgical field on a monitor.

There are currently five surgical systems in clinical use in Scotland within intracavity surgery:

- DaVinci® RAS system in NHS Greater Glasgow and Clyde, providing a regional service for the West of Scotland;
- DaVinci® and Versius®RAS systems in NHS Lothian, providing a regional service for the East of Scotland;
- DaVinci® RAS system in NHS Grampian, providing a regional service for the North of Scotland;
- DaVinci® RAS system in Golden Jubilee National Hospital, providing specialist thoracic surgery (since 2018).

The three regional robots initially focused on robotic assisted radical prostatectomy, linked to the combined funding streams of Scottish Government (SG), charities and local health board funds. NHS Grampian expanded earlier into undertaking partial nephrectomies and hysterectomies via RAS. Over 2018/19, the Edinburgh and Glasgow teams have commenced RAS partial nephrectomy.

NHS Lothian has also recently commenced a partnership with the Versius® Surgical robotic system. The programme is starting with RAS for rectal cancer.

Indications

RAS is used in a growing number of indications in Scotland and further afield. However, given the current interests of the National Planning Robotic Review group, the use of robotic assisted surgery in gynaecological, colorectal and urological procedures was the focus for this evidence review.

Outcomes

No specific outcomes were identified by the group and therefore all clinical outcomes reported within the literature were considered to be of potential interest. Service related and cost outcomes were reported where they were presented alongside clinical outcomes.

Identified Studies

The Scottish Health Technologies Group (SHTG) has previously reviewed the use of RAS for undertaking radical prostatectomy,[1] partial nephrectomy[2] and for colorectal cancer procedures.[3] These reviews include some limited information on volumes and outcome relationships. This review updates these previous reviews and also looked for any recent evidence for additional urological procedures and gynaecological procedures. Secondary evidence (already synthesised) was sought initially, with primary studies only being included where no such synthesised evidence was available.

The literature search identified 410 potentially relevant records. These were screened by a researcher and 26 were selected for further consideration. On examining the full text of these papers, eight were retained, and the other 18 were excluded. Of the eight retained papers, three were systematic reviews, three were retrospective observational studies and two were cost analyses. Citation searching undertaken on included studies identified a further four relevant retrospective observational studies.

Gynaecological procedures

No systematic reviews meeting the inclusion criteria were identified.

Several primary studies were retrieved which considered the impact of volume of gynaecological minimally invasive surgical procedures on outcomes,[4, 5] but these did not present results separately for robot-assisted procedures, so are not considered further here.

One retrospective observational study[6] examined the outcomes of all robotic-assisted sacrocolpopexy procedures performed from June 2010 to August 2015 by a single surgeon at two different institutions within a health system in the United States. One hospital had a dedicated robotic team and the other did not. Mean operative time for the dedicated team was statistically significantly shorter (131.8 vs 160.2 minutes, $p < 0.001$). Multivariable linear regression analysis was used to identify factors impacting on the operative time, and the reduced time for the dedicated team persisted after adjusting for other factors. Operative complications and prolapse recurrence were low overall and a statistically significant difference was not seen between teams.

Colorectal procedures

No systematic reviews meeting the inclusion criteria were identified.

One primary retrospective observational study[7] was identified which used the US National Cancer Database to examine outcomes for patients receiving minimally invasive colorectal surgery between 2010 and 2015. However this did not report results separately by modality of surgery, so is not further considered here. A comprehensive NICE Evidence review[8] considered the impact of surgical volumes and outcomes but does not report any information relating specifically to RAS.

While no further studies were identified by the literature search, citation searching did reveal one relevant primary study. Bastawrous *et al*[9] sought to assess the effect of surgeon volume on outcomes of robotic colorectal operations performed by surgeons with low or high volume, across a large health system. They performed a retrospective review of colon or rectal resections performed between January 1, 2013 and January 1, 2017 within the Providence Health System Hospitals in the United States. Procedures were separated into those performed by surgeons with high volume (30 or more robotic cases per year) versus low volume (fewer than 30 robotic cases per year). A total of eight surgeons classed as performing a high volume of procedures and 41, a low volume of procedures, were included in the study, conducting in total 957 procedures, and results were divided up by the four separate procedures considered.

Table 1: Impact of volume on outcomes (Bastawrous et al)

Procedure	Operative times (high versus low volume surgeons)	Conversion rates (high versus low volume surgeons)	Length of stay (high versus low volume surgeons
Right colectomy	186 vs 249 min, p < 0.05	2.6% vs 13.1%, p = 0.0003	4.3 vs 5.9 days, p = 0.016
Left colectomy	184 vs 246 min, p < 0.05	8.9% vs 10.7%, p = 0.75	4.6 vs 5.4 days, p=0.30
Low anterior resections	265 vs 288 min, p = 0.03	3.5% vs 10.4%, p =0.01	4.7 vs 6.1 days, p = 0.01
Abdominal perineal resections	303 vs 333 min, p = 0.17	5.4% vs 4.3%, p= 0.79	5.4 vs 8.6 days, p = 0.01

Patients treated by high volume surgeons had a significantly shorter length of hospital stay, lower conversion rate, and lower total hospital cost. For all procedures, there was no statistically significant difference observed for complication and readmission rates between patients treated by high and low volume surgeons.

Urological procedures

Radical prostatectomy

A previous SHTG report[1] included a systematic review incorporating studies published between 1997 and 2007 (Wilson *et al*, 2010) and a regression analysis based upon 8,032 radical prostatectomy cases recorded between 2004 and 2009. It also identified a systematic review, a narrative literature review and a study that combined case series, which examined learning curve effects. Full details are available within the SHTG publication.

One new systematic review[10] examining volume/outcome relationships for radical prostatectomy was identified. However, it included studies considering all types of radical prostatectomy and did not separate out the results by open, laparoscopic and robotic-assisted laparoscopic surgery. The review authors reported that most of the studies demonstrated that higher-volume surgeries are associated with better outcomes including reduced mortality, morbidity, postoperative complications, length of stay, readmission, and cost-associated factors, and that the volume–outcome relationship is maintained in robotic surgery. While results are not reported separately by surgical type, within the discussion section, the review authors discuss the impact of type of surgery on the volume/outcome relationship, noting a number of the primary studies that they have included in the review where this can be drawn out. Apart from Cole *et al* (2016) which is discussed below, these studies were all published prior to the inclusion date for this report, but the information about them given in the systematic review is reproduced below for information.

> "Prior analysis has demonstrated that institutions performing robotic-assisted radical prostatectomy or open radical prostatectomy at low volumes had inferior outcomes relative to high-volume institutions (Sammon *et al*, 2013). More recent studies examine robot assisted radical prostatectomy outcomes largely as a subset of overall radical prostatectomy, and identify significant associations between high-volume surgeons and hospitals with shorter median procedural times ($p < 0.001$) (Carter *et al* 2014), lower readmissions (Fridriksson *et al*, 2014), negative surgical margins (Evans *et al*, 2014) and higher immediate continence ($p < 0.042$)(Hatiboglu *et al*, 2014). Three investigators assessed robotic-assisted radical prostatectomy in isolation. They demonstrated that volume was an independent predictor of shorter length of stay and reduced costs (Fridriksson *et al*, 2014; Badaus *et al*, 2011), with one study estimating that $19 million could be saved annually if all robotic-assisted radical prostatectomies were performed at high-volume institutions (Cole *et al*, 2016; Hyams *et al*, 2013; Yu *et al*, 2012)."

Five primary studies published after January 2016 and relevant to the current question were identified.

Xia *et al*[11] identified robotic-assisted radical prostatectomies to treat patients with clinically localised (cT1-2N0M0) prostate cancer diagnosed between 2010 and 2014 and recorded in the National Cancer Database in the United States. A total of 114,957 patients were included in the study, and hospital volume was categorised into very low (3 to 45 cases per year), low (46 to 72), medium (73 to 113), high (114 to 218) and very high (219 or more). Overall 30-day mortality (0.12%), 90-day mortality (0.16%) and conversion rates (0.65%) were low. Multivariable logistic regressions showed that compared with the very low volume group, higher hospital volume was associated with lower odds of conversion to open surgery (Odds Ratio (OR) 0.23, p <0.001 for very high), prolonged length of stay (OR 0.25, p <0.001 for very high), 30-day readmission (OR 0.53, p <0.001 for very high) and positive surgical margins (OR 0.61, p <0.001 for very high). Higher hospital volume was also associated with higher odds of lymph node dissection in the intermediate/high risk cohort of patients (OR 3.23, p <0.001 for very high).

Gershman *et al*[12] also undertook a retrospective review of RAS prostatectomy cases, this time considering records from the US Nationwide Inpatient Sample for 140,671 men who underwent robotic- assisted radical prostatectomy from 2009 to 2011. The associations of hospital volume with perioperative outcomes and total hospital costs were evaluated using multivariable logistic regression and generalised linear models. Annual hospital volume was categorised into volume quartiles as follows: very low 12 or fewer case, low 13 to 30 cases, medium 31 to 66 cases and high 67 to 820 cases. Compared to patients treated at the lowest quartile hospitals, those treated at the highest quartile hospitals had significantly lower rates of intraoperative complications (0.6% vs 1.4%, ptrend <0.001), postoperative complications (4.8% vs 13.9%, ptrend <0.001), perioperative blood transfusion (1.5% vs 4.0%, ptrend <0.001), prolonged hospitalisation (4.3% vs 13.8%, ptrend <0.001) and mean total hospital costs ($12,647 vs $15,394, ptrend <0.001). When modelled as a nonlinear continuous variable, increasing hospital volume was independently associated with improved rates of each perioperative end point up to approximately 100 robot-assisted radical prostatectomies per year, beyond which there appeared to be marginal improvement.

Simon et al,[13] based upon data gathered in retrospective study of outcomes of 2,619 men treated at six Veterans Affairs hospitals in the US, found that hospital volume was inversely associated with operative time for robotic-assisted prostatectomy. Each additional case per year per centre being associated with a 48 second decrease in operative time. The study authors included this variable, alongside others, in a nonogram that they developed to predict overall operative time.

A cost analysis undertaken by Cole *et al*[14] was based upon sample of 291,015 men from the Premier Hospital Database who underwent robot-assisted radical prostatectomy for prostate cancer by 667 surgeons at 197 U.S. hospitals from 2003 to 2013. They found that nearly a third of the variation in robot-assisted radical prostatectomy cost was attributable to hospital characteristics such as teaching status, location, size, prostatectomy volume and more than a fifth was attributable to surgeon characteristics such as volume of prostate surgery undertaken (r-squared 30.43% and 21.25%, respectively). High volume surgeons and hospitals (90th percentile or greater) had decreased odds of high cost surgery (greater than 18,621 USD) (surgeons: OR 0.24, 95% CI 0.11-0.54; hospitals: OR 0.105, 95% CI 0.02-0.46).

Using Australian data, Basto *et al*[15] describe an economic model from which they concluded that robotic-assisted prostatectomy surgery can become cost - equivalent to open surgery when more than 140 cases per year are performed.

Radical cystectomy

One systematic review was identified[16] where the authors examined rates of radical cystectomy complications and investigated the impact of surgical volume and surgery type on these rates. They included 49 studies, but only two of these assessed the impact of surgical volume on perioperative outcomes. The review authors report that in the first of these studies (Hayn *et al* 2011) there was a longer operative time but no differences in operative and postoperative complications in the first 100 robotic-assisted radical cystectomies compared with the subsequent 100 procedures performed at the same institution. Based upon the same institution, a second study (Azzouni *et al*, 2013), evaluated the first 100 consecutive patients treated with robotic-assisted radical cystectomy and robotic-assisted intracorporeal ileal conduits (RICIC). Patients were stratified in quartiles, and no differences were recorded in terms of readmission at 30 days, readmission at 90 days, or perioperative complications. Given that only 100 patients from a single institution were included in this study, the study authors concluded that further evaluation was needed to assess the impact of surgical volume on perioperative complications after RICIC.

No more recent relevant primary studies were identified.

Partial nephrectomy

A previous SHTG Evidence note[2] identified two relevant studies.

The current literature search did not identify any other relevant papers; however citation searching did identify two more recent studies.

Peyronnet *et al* [17] aimed to assess the impact of hospital volume (HV) and surgeon volume (SV) on perioperative outcomes of robot-assisted partial nephrectomy (RAPN). Their study was based upon a retrospective analysis of all consecutive patients (n=1,222) who underwent a RAPN from 2009 to 2015, at 11 institutions in France. To evaluate the impact of HV, the authors divided RAPN into four quartiles according to the caseload per year: low HV (<20/year), moderate HV (20-44/year), high HV (45-70/year), and very high HV (>70/year). The SV was also divided into four quartiles: low SV (<7/year), moderate SV (7-14/year), high SV (15-30/year), and very high SV (>30/year). The primary endpoint was the

Trifecta defined as the following combination: no complications, warm ischaemia time (WIT) <25 minutes, and negative surgical margins.

The study authors found the mean (standard deviation (SD)) caseload per hospital per year was 44.9 (26.7) for RAS partial nephrectomies, and the mean (SD) caseload per surgeon per year was 19.2 (14.9). The Trifecta achievement rate increased significantly with SV (69.9% vs 72.8% vs 73% vs 86.1%; $P < 0.001$) and HV (60.3% vs 72.3% vs 86.2% vs 82.4%; $P < 0.001$). The positive surgical margins (PSM) rate ($p = 0.02$), length of hospital stay (LOS; $p < 0.001$), WIT ($p < 0.001$), and operative time ($p < 0.001$), all decreased significantly with increasing SV. The PSM rate ($p = 0.02$), LOS ($p < 0.001$), WIT ($p < 0.001$), operative time ($p < 0.001$), and major complications rate ($p = 0.01$), all decreased significantly with increasing HV. In multivariate analysis adjusting for HV and SV, HV remained the main predictive factor of Trifecta achievement (OR 3.70 for very high vs low HV; $P < 0.001$), whereas SV was not associated with Trifecta achievement (OR 1.58 for very high vs low SV; $P = 0.34$).

Xia *et al* [18] undertook a retrospective cohort analysis study to investigate the relationship between hospital volume and robotic-assisted partial nephrectomy outcomes, based upon data gathered in the American National Cancer Database (NCDB). The NCDB is a prospectively maintained nationwide and hospital-based database that captures 70% of all newly diagnosed malignancies in the USA each year. A total of 18,724 patients were included in the final cohort for analysis. Hospital volume categories were determined according to the following criteria: very low volume, 1–7 cases (n = 3,693); low volume, 8–14 cases (n = 3,719); medium volume, 15–23 cases (n = 3,833); high volume, 24–43 cases (n = 3,649); and very high volume, ≥44 cases (3,830). There was no significant difference in 30-day or 90-day mortality among the five groups. Multivariable logistic regression analysis showed that higher hospital volume was associated with lower odds of conversion (low [OR 0.88; $p = 0.377$]; medium [OR 0.60; $p = 0.001$]; high [OR 0.57; $p < 0.001$]; very high [OR 0.47; $p < 0.001$]), lower odds of prolonged length of stay (low [OR 0.93; $p = 0.197$]; medium [OR 0.75; $p < 0.001$]; high [OR 0.62; $P < 0.001$]; very high [OR 0.45; $p < 0.001$]), and lower odds of positive surgical margins (low [OR 0.76; $p < 0.001$]; medium [OR 0.76, $p < 0.001$]; high [OR 0.59; $p < 0.001$]; very high [OR 0.34; $p < 0.001$]). Sensitivity analyses confirmed increasing hospital volume (per 1-case increase) was associated with lower odds of conversion (OR 0.986; $p < 0.001$), prolonged length of stay (OR 0.989; $p < 0.001$) and positive surgical margins (OR 0.984; $p < 0.001$).The authors conclude that undergoing RAPN at higher-volume hospitals may lead to better peri-operative outcomes (conversion to open and LOS) and lower positive surgical margin rates, but further studies are needed to explore the detailed components that lead to the superior outcomes in higher-volume hospitals.

Learning curve

One recent systematic review was identified which sought to investigate surgeon learning curves in robotic surgery. Soomro *et al* [19] searched for studies published between 1st January 2012 and 5th February 2018. Forty-nine relevant studies were retrieved, all of them observational, of which 40 were retrospective and 9 nine prospective. Most studies involved fewer than five surgeons, with more than half having fewer than three. Ten different surgical specialties were represented. Time-based metrics were the most commonly reported variables used to assess the learning curve, reported by 42 of the 49 studies. Other measures, including length of hospital stay, morbidity and mortality rates, and procedure-specific metrics, were reported less commonly. The authors of the review found standards of reporting within the studies were generally poor. For example only 35% of studies noted if the surgeon had previous experience. The methods used within many of the studies were also questioned by the review authors, with statistical validation often lacking, ambiguous terminology used and a wide variety of thresholds employed. The review authors note that the reported learning curves showed substantial heterogeneity, varying between procedures, different studies and according to the metrics used. They indicate the need for robust research in this area, and detailed reporting of surgeon experience, patients included and procedure complexity

Conclusion

A search for evidence published after 1st January 2016 which considered the impact of surgeon/hospital volume on the outcomes achieved in robotic assisted gynaecological, colorectal or urological cancer, revealed only a small number of publications, most of them with methodological issues affecting their validity.

For gynaecological and colorectal cancer in particular, the literature was very limited. The evidence base is more developed for urological procedures, reflecting the longer time period over which RAS has been used in this field. A number of publications were identified which considered the impact of the volume of minimally invasive procedures, or indeed open and minimally invasive procedures in general on outcomes, but for the most part, these did not report the data on RAS separately preventing it from being incorporated into this review.

Drawing conclusions from this evidence is challenging for a number of reasons. Firstly, there is a large variation across studies in how volume was quantified. Some studies use medians, or divisions such as tertiles, quartiles and deciles. Others employ, what appear to be fairly arbitrary cut offs, and a further set consider volume as a continuous variable. Use of a continuous variable approach enables comparison across studies, but with the other divisions, this is difficult. Secondly, while the included publications are fairly recent, much of the data on which they are based dates back to pre-2014. Both the technology and understanding of its use have moved on since then. There are also issues regards the generalisability of the findings. Outcomes relating to the delivery of care such as length of stay, operative time and costing data, are likely to be highly dependent on the local context. A high proportion of the identified literature for this review related to data gathered in the United States.

Most of the studies are retrospective observational studies and are subject to the biases inherent in such study types. Reporting issues are common, with insufficient detail provided on, for example, the prior experience of the surgeon or hospital under study, and of the condition of the patients on which the procedures are being undertaken. The overall accuracy and comprehensiveness of the reporting is uncertain. There are also concerns around selection bias and whether the patients included are similar to those in the other groups in which outcomes are being compared, or for example, whether more experienced surgeons are operating on more severally unwell patients. Lastly, confounding by the many other variables which could potentially account for the outcomes seen needs to be recognised and adjusted for in analyses. There is likely to be considerable interaction between the type of hospital system in which a surgeon is operating, the volume of the particular procedure under study performed within that system, and the skills, experience and knowledge of the surgeon and their colleagues.

Given these concerns it is necessary to consider the evidence presented as indicative rather than definitive in its utility in contributing to decision making within NHSScotland.

Equality and diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation.

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