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**Robotic TAMIS – technical, oncological and patient outcomes from a single institution.**

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Key words: rectal tumour, rectal polyp, dysplastic lesion, transanal resection, robotic surgery, TEMS, TAMIS.

## **Abstract**

### **Introduction**

Robotic transanal minimally invasive surgery (R-TAMIS) is gaining traction around the globe as an alternative to laparoscopic conventional TAMIS (L-TAMIS) for local excision of benign and early malignant rectal lesions.

**Aims:** To analyse patient and oncological outcomes of R-TAMIS in a single centre of consecutive cases.

**Methods:** A prospective analysis of consecutive R-TAMIS procedures over a 12-month period was performed. Data was collated from hospital databases and theatre registers.

**Results:** Eleven patients (6M, 5F), mean age 69.81 years (51 -92years) underwent R-TAMIS over 12 months utilising a Da Vinci Xi platform. The mean lesion size was 36mm (20mm – 60mm) with a mean distance from anal verge of 7.5cm (3- 14cm). Five lesions were posterior in anatomical location, 4 anterior, one right lateral and one left lateral. All procedures were performed in the lithotomy position using a GelPOINT path platform. Mean operative time was 64 minutes (40 – 100mins). Complete resection was achieved in 10/11 patients with two patients being upgraded to a diagnosis of adenocarcinoma. Nine patients were diagnosed with dysplastic lesions. Four patients had a false positive diagnosis of an invasive tumour on MRI. Six patients required suturing for full thickness resections. One patient had a bleed post-op requiring repeat endoscopy and clipping. One patient (full thickness resection of T3 tumour) proceeded to a formal resection without difficulty with no residual disease (T0N0, 0/22). One patient with a fully resected T2 tumour is undergoing surveillance protocol. The mean length of stay (LOS) was 1 day with two patients having a LOS of 2 days and one patient of 4 days.

**Conclusion.** R- TAMIS could potentially represent a safe novel approach for local resection of rectal lesions.

### **Introduction**

Colorectal cancer (CRC) is responsible for a significant burden of disease and is the second most common cause of cancer related death in Australia. Approximately 46% of all CRC diagnoses are early stage (stage I or II), an increasing percentage due to early detection

through the National Bowel Cancer Screening program. Additionally, the rectum is the most common CRC subsite, representing 26% of diagnoses<sup>1</sup>. Similar findings are documented in the United Kingdom<sup>2</sup>. In light of the apparent increasing incidence of early stage rectal cancer it is no surprise that the surgical community is adopting organ preservation techniques for treatment of dysplastic and early rectal cancer lesions. Through the development of natural orifice approaches it is possible to offer surgical treatment with less morbidity than traditional transabdominal approaches by avoiding stomas, bladder/bowel/sexual dysfunction and decreasing hospital length of stay.

The use of a standard single port device, such as TAMIS, has been shown to have similar patient and oncological outcomes to TEMS in smaller studies, confined to the lower 1/3 of the rectum<sup>4,5</sup>. TAMIS has multiple advantages over TEMS due to the relatively easier patient positioning and inexpensive set-up costs due a single use platform and the ability to use standard laparoscopic instruments. Furthermore, additional advantages of TAMIS over TEMS include rapid set-up time and 360 degrees vs. 220 degrees of visibility within the rectal lumen which greatly reduces operative timing of TAMIS<sup>6,7</sup>. Such surgical approaches have shown favourable outcomes in the literature and despite larger lesions being associated with increased risk of margin positivity there are no significant surgical dissection nor histological analysis impediments in those requiring further radical resection for invasive disease<sup>8</sup>.

With the advent of robotic surgical platforms, robotic transanal minimally invasive surgery (R-TAMIS) is gaining interest globally as a potential alternative to conventional laparoscopic TAMIS (L-TAMIS) for local excision of benign and early malignant rectal lesions. This technique involves full-thickness resection of the tumour or submucosal resection for benign lesions and its margins down to perirectal fat without the need for proctectomy. Initially performed on cadavers, the reported benefits of R-TAMIS include improved ergonomics and clearer views, tremor elimination and increased manoeuvrability of instruments with multiple degrees of freedom<sup>7-9</sup>. The aim of this study was to analyse patient and oncological outcomes of R-TAMIS using a da Vinci Xi™ surgical robotic platform in a single centre of consecutive cases.

## Methods

Eleven patients deemed suitable for conventional L-TAMIS were consented and underwent R-TAMIS (see inclusion criteria below). Patients received mechanical bowel preparation and prophylactic antibiotics. All procedures were conducted under general anaesthesia utilising the da Vinci Xi™ surgical robotic system (Intuitive Surgical, Sunnyvale, CA, USA). A urinary catheter is inserted with the patients placed in a lithotomy position. The anus is everted with four 0-silk sutures placed in four quadrants to retract the anus. The anal canal is washed with cetrimide. The GelPOINT Transanal Access Platform is then inserted using sponge forceps and position confirmed using the dilator (*GelPOINT Path platform (Applied Medical, Rancho Santa Margarita, CA, USA. 4x5.5cm)*). Two standard 8mm da-Vinci working ports were placed at 3 and 9 position on the TAMIS platform, an 8mm bariatric port placed at 12 position to facilitate the camera and a 12mm Airseal Port (assistant port) was inserted at 6 (Fig 1A). A 30-degree camera is utilised in all cases. A pneumorectum is established with an AirSeal® i.F.S (AirSeal® i.F.S (*Intelligent Flow System*), Conmed, Connecticut, USA), at a pressure of twelve millimeters of mercury. The da-Vinci Xi platform was docked from the patients left with arm four left redundant and to the left side. The camera port was connected and under direct vision the robotic scissors via the right working 8mm port and grasper via left working 8mm port was advanced to the polyp base (Fig 1B, C).

The lesion was raised using mucosal lift technique by passing an endoscopic injector device via the Airseal port and infiltrating either glycine or normal saline and methylene blue (Figure 2A). The mucosa was circumferentially marked with diathermy to ensure a macroscopic clear resection margin and the lesion dissected from superficial to deep layer using robotic scissors (Fig 2B). Once resection was completed the lesion was extracted via the transanal platform and secured to a cork board using tacks to ensure anatomical margin positioning. When complete haemostasis was achieved, all full thickness defects were closed in a continuous fashion using 3-0 absorbable V-Loc suture and spongostan placed (Fig 2c). A pudendal nerve block was performed to reduce post-operative pain at the end of the procedure. Operative time was defined as the time taken from commencing prepping and draping the patient to undocking the robot post procedure.

All patients were observed as an inpatient overnight and commenced on 72 hours of oral metronidazole and a stool softener. All patients are seen two weeks post-op for clinical assessment and evaluation of the histology of the resected specimen.

**Inclusion criteria:**

Patients >16 years of age,

Lesion location: Rectal mass less than 18cm from Anal Verge

Benign disease: Polyps without submucosal invasion or excisional biopsy of uncertain malignant potential.

Malignant disease: uT1No tumor staging, favorable characteristics such as no LVI or poor differentiation.

High risk patients deemed unfit for radical resection.

Patient preference.

**Results**

Eleven patients (6M, 5F), underwent robotic TAMIS for rectal lesions identified on colonoscopy over a 12-month period with a mean age of 69.81 years (51 -92 years, Table 1). Mean lesion size was 36mm (20mm – 60mm) with a mean distance from the anal verge of 7.5cm (3-14cm). Five lesions were posterior in anatomical location, 4 anterior, one right lateral and one left lateral. All procedures were performed in the lithotomy position.

**Table 1 Patient demographics and tumour characteristics**

Patient	1	2	3	4	5	6	7	8	9	10	11
Age	65	63	51	74	61	63	76	69	90	64	92
Sex	M	M	F	M	M	F	F	F	M	F	M
BMI	28	31	39	25	21.8	26.5	19.3	30.2	20	27.1	20.8
Location	Anterior	Posterior	Anterior	Anterior	Anterior	Posterior	Posterior/ right lateral	Posterior	Left lateral	Posterior left lateral	Posterior
Size (mm)	50x47x12	20x13x13	30-62x4	28x24x19	23x22x10	25x22x4	60x55x10	34x17x6	35x25x16	20x15x12	32x35x10
Distance*	10	7	8	10	4	14	8	7	5	4	3

\*Distance from anal verge

On pre-operative MRI six patients were diagnosed with invasive disease (T1=3, T2=2, T3=1, Table 2). The patient with T3 invasive disease was advised to undertake formal resection however declined opting for R-TAMIS as the initial biopsy showed benign disease, one patient with T2 disease had a benign appearing lesion on endoscopy and the second patient with T2 disease was 92-year old and not fit for formal resection. Complete resection was achieved in 10/11 patients. Nine patients were diagnosed with dysplastic lesions. Four patients had a false positive diagnosis of an invasive tumour (T1=3, T2=1).

Of the two patients diagnosed with invasive adenocarcinoma, the patient with a pre-operative MRI displaying T3 disease had incomplete margins with low grade adenocarcinoma (pT3) extending to the resection margin and underwent a formal robotic ultralow anterior resection without complication. Final histology revealed no residual disease – T0N0 (0/27). The second patient with a diagnosis of invasive malignancy was a 92yo male with a completely resected T2 tumour with favourable characteristics and has opted for surveillance.

**Table 2 Pathological outcomes**

Patient	1	2	3	4	5	6	7	8	9	10	11
Grade on MRI	T2	T3	T1 Recurrence	Benign	Benign	Benign	T1	Benign	Benign	T1	T2
Margins	Complete	Incomplete	N/A	Complete	Complete	Complete	Complete	Complete	Complete	Complete	Complete
Histopathology	TVA, LGD + HGD	Ac, LGD to resection margin, No LVI pT3	HGD	TVA, LGD	TVA, LGD	TVA, LGD	TVA, LGD + fragments HGD	TA, HGD	TA, HGD	TA, HGD	Ac pT2

**TVA – tubulovillous adenoma, TA - tubular adenoma, Ac – adenocarcinoma, HGD – high grade dysplasia, LGD – low grade dysplasia.**

All procedures were performed in the lithotomy position utilising a Gel POINT path platform (Figure 1, Table 3). Mean operative time was 64 minutes (40 – 100mins).

Six patients required suturing for full thickness resections. Mean length of stay (LOS) was 1 day with 2 patients having a LOS of 2 days and 1 patient having a LOS of 4 days. One patient had a bleed post-op requiring flexible sigmoidoscopy and clipping of the offending vessel. No patient required a readmission post R-TAMIS.

**Table 3 Operative outcomes**

Patient	1	2	3	4	5	6	7	8	9	10	11
Position	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy	Lithotomy
Platform	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP	TAMIS-GP
Closure	no	no	sutured	sutured	sutured	no	no	no	sutured	sutured	sutured
Operative time (min)	90	50	60	80	40	100	40	45	50	50	100
LOS	1	1	1	4	1	2	1	1	1	1	2
Complications	nil	nil	nil	nil	nil	Bleeding: endoscopy clipping	nil	nil	nil	nil	nil
Re-admission	no	no	no	no	no	no	no	no	no	no	no

**TAMIS-GP – transanal GelPOINT Path (Applied Medical, Rancho Santa Margarita, CA) platform.**

## Discussion

The first successful human application of R-TAMIS was reported by Atallah et al. in 2012, in a single case study with an operative time of 105 minutes and without complication<sup>10</sup>. This was quickly followed by a small multi-centre study across UK, Switzerland and USA by Hompes et al. in 2014, who performed R-TAMIS with a glove port on 16 patients with rectal tumours between 3-10cm from the anal verge (FAV)<sup>11</sup>. The median operative time was 108 minutes (40-180), median hospital stay was 1.3 days and only 2 minor complications of urinary retention requiring catheterisation. Patient position varied across centres, USA utilised prone for all patients however UK and Switzerland utilised prone only for anteriorly located lesions and left lateral decubitus for posterolateral lesions. The da Vinci Si surgical robot (Intuitive Surgical, Sunnyvale, CA, USA) and a glove port was used in all cases.

In a retrospective cohort study comparing L-TAMIS to R-TAMIS in 40 consecutive patients, Lee et al. reported no difference in terms of peri-operative parameters or 30-day post-operative outcomes<sup>12</sup>. Total direct cost however was raised as the major distinction with R-TAMIS costing US\$880 more than L-TAMIS per procedure. The authors discussed the potential impact of the ongoing learning curve with R-TAMIS and the view that in appropriately selected patients R-TAMIS may save patients from radical resection, especially when L-TAMIS is not feasible.

In 2018 an Australian study described an R-TAMIS technique using the new dVXi™ robot (Intuitive Surgical, Sunnyvale, CA, USA) and Airseal system on eight patients in prone jack-knife position. The authors reported R-TAMIS to be safe and feasible with the advantages of a stable pneumorectum without bellowing and clearer views with the AirSeal system and improved ergonomics through the articulating robotic arms which is particularly advantageous for dissection of the upper segments of the lesion<sup>13</sup>. A multi-institutional series by Liu et al., who also utilised the dVXi™ platform on 34 patients, utilised a lithotomy position in 94% of cases and a prone position in 6% of the cohort<sup>14</sup>. The average operative time was  $100 \pm 70$  min with robotic console time of  $76 \pm 67$  min. The authors reported that increased patient body mass index (BMI) resulted in nearly doubled operating time and was most likely due to patient positioning in lithotomy causing limited distance between the patient's legs therefore restricting the robotic arms. The authors stated that the learning curve is faster for R-TAMIS compared to L-TAMIS, however do not comment on the potential cross over of skills. Similarly, the largest study to date of 58 patients reported similar

operative times, excellent rate of intact specimen retrieval and 94.8% margin negativity rate<sup>15</sup>.

Our results are similar to those reported in the literature in respect to operative time and LOS without major postoperative complications apart from a bleed from the resection site requiring endoscopic clipping. The majority of reported complications are Clavien classification Grade 1 or 2 including urinary retention<sup>11,16</sup>, pneumoperitoneum conservatively managed<sup>11,17</sup>, clostridium difficile infection<sup>14</sup>, self-limiting post-operative rectal bleeding<sup>16</sup>, and surgical line dehiscence with tenesmus treated with antibiotics<sup>16</sup>. Grade 3 complications include delayed bleeding from surgical site requiring intervention<sup>16</sup> or involved margins resulting in TME<sup>11,17</sup>.

The preferred imaging for early rectal cancer staging is either high-resolution MRI<sup>18</sup> or endorectal ultrasound (ERUS)<sup>19</sup>, or both as complementary tools due to the conflicting evidence in the literature<sup>20</sup>. MRI may have difficulty specifying the depth of invasion and clearly delineating between T1/ T2 disease and T2/early T3 disease. Whereas ERUS is operator dependent, is less accurate for large bulky lesions and stenotic lesions prevent adequate probe positioning and suboptimal staging. Both have difficulty distinguishing between tumour and peritumour inflammatory or fibrotic response and both over/understage lesions<sup>20,21</sup>. A UK study (2017) looked at the ability of experienced radiologists to predict early stage rectal cancer with high-resolution MRI sequences in 64 patients. They found high-resolution MRI images had 89% accuracy, 71% sensitivity and 94% specificity for identifying a safe submucosal plane for T1sm1-sm2 tumours. Prediction of node negative status was >80%<sup>18</sup>. In contrast a recent Norwegian study (2019) found ERUS to be superior at detecting adenoma and T1 (80%) disease in comparison to MRI (74%). They commented on the potential for bias towards overstaging when the clinical picture is suggesting malignancy and there is interobserver variability of MRI reports<sup>21</sup>. In our study, four patients were overstaged with MRI (T1=3, T2=1), all of them adenoma on final histopathology, this has been reported as a limitation of MRI in this setting<sup>21,22</sup>. Given the known limitations of each modality, the conflicting evidence in the literature and the potential impact on patient management; discussion at MDT and the patient may help decide if both MRI and EUS would be beneficial in lesions deemed T1/T2. With a benign appearance endoscopically or on biopsy it is better to clarify if TAMIS is appropriate. Additionally, if ERUS should be favoured to MRI in the setting of a suspected adenoma<sup>21,22</sup>. It will be interesting to see how advancement of imaging techniques such as the inclusion of real-time elastography impact on this area.

Multiple studies have reported using nerve blocks at the commencement of the case to aid sphincter relaxation and decrease post-operative pain, however no comments on whether this benefited the operative task have been reported<sup>11,13</sup>. The lithotomy position was chosen because of the ease of conversion to formal resection which is in contrast to some authors who opted for prone or lateral positioning stating this was the ideal to avoid robotic arm clash and assistant comfort. It is the authors experience that anterior lesions can be resected in the lithotomy position provided that the left working arm entering at 9 o' clock has full manoeuvrability to retract the lesion in a downward position from the operators right to left (patients left to right). This allows dissection using the working port entering at 3 o'clock. The operating field space is greatly increased by using a bariatric port for the camera insertion thus offsetting the ports and prevents clashing. Furthermore, the ability to switch to a 30 degree up view on the camera greatly facilitates this dissection. Finally, when suturing full thickness defects anteriorly the authors suggest using a back handed approach with the needle driver at 3 o'clock and suturing from the operators left to right to prevent clashing. Defining the position of robotics in colorectal surgery is an ongoing process and the current lack of prospective randomised trials comparing R-TAMIS to L-TAMIS contributes to this. However, the learning curve for surgeons transitioning to R-TAMIS is determined not only by surgeon expertise and natural learning process but also by access to the technology with the cost of system being the major contributor. The ROLARR randomised control trial (RCT) compared robotic-assisted to conventional laparoscopic anterior resection or abdominopelvic resection across 29 sites in 10 countries including 471 patients<sup>23</sup>. The results failed to show robotic-assisted surgery to confer an advantage over conventional laparoscopic surgery in terms of reduced conversion to open nor secondary outcomes of reduced complication rates or improved quality of life at 6 months. However, Chand et al. highlight the design fault of comparing experienced laparoscopic surgeons with less experienced robotic surgeons and an in-depth statistical analysis adjusting for potential learning effects found that robotic-assisted surgery did indeed confer a benefit over standard laparoscopic surgery in terms of risk of conversion to open when performed by a surgeon with substantial robotic surgery experience<sup>24,25</sup>. It is reasonable to expect that with the continued recruitment of robotic technology by hospitals, surgeons will become as proficient with the technology as they are with conventional laparoscopic and open techniques and that a robust RCT will be carried out. However, with the evolution of technology potentially conveying the agility of robotic instruments to laparoscopic instruments, the benefit of robotics may be outweighed

by cost alone even when the learning curve has been overcome<sup>24</sup>. A review of the system costs alone (not including hospital costs) estimate US\$3568 per procedure which is significantly more than the standard laparoscopic procedures<sup>26</sup>. However, there is a notable lack of competition in the market and unusual limitations imposed by the company regarding the timeframe around instrument replacement. Note there may also be a reduction in theatre time for complex cases where the robot is used, which may alleviate the cost of the robot. Perhaps with the passage of time and the development of cheaper robotics, cost too will be an irrelevant factor and we can focus on the benefit the technology adds to the skill of the surgeon.

Limitations of this study include the small sample size of retrospective case cohort and short duration of follow up. This is a consistent limitation of these studies and as discussed, the need for a RCT once the robotic learning curve is overcome is inevitable.

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Figure 2



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