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Establishing and integrating a transoral robotic surgery programme into routine oncological management of head and neck cancer – a UK perspective

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Main Article

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Abstract

Background. The introduction of transoral robotic surgery into routine management of patients is complex. It involves organisational, logistical and clinical challenges. This study presents our experience of implementing such a programme and provides a blueprint for other centres willing to establish similar services.

Methods. Implementation of the robotic surgery programme focused on several key domains: training, logistics, governance, multidisciplinary team awareness, pre-operative imaging, anaesthesia, post-operative care, finance, patient selection and consent. Programme outcomes were evaluated by assessing operative outcomes of the first 117 procedures performed.

Results. The success of the transoral robotic surgery programme has been possible because of the scrupulous planning phase before the first procedure, and the time invested on team awareness and training.

Conclusion. Implementation of a new transoral robotic surgery service has led to: the development of a dedicated transoral robotic surgery patient care protocol, the performance of progressively more complex procedures, the inclusion of transoral robotic surgery training and the establishment of several research projects.

Introduction

The incidence of head and neck cancers is rising in the UK, and there are currently around 12 200 new cases every day.[1] Although smoking rates are decreasing, oropharyngeal cancer is increasing, especially in men, and tends to be related to P16 or high-risk human papillomavirus (HPV).[2,3] Patients who undergo non-surgical as well as open invasive head and neck surgical treatment frequently present with significant physical, functional and psychological morbidity, as highlighted by qualitative studies.[4,5]

Transoral robotic surgery was first used clinically in 2005.[6] The US Food and Drug Administration subsequently approved the da Vinci® surgical robot for resection of T_1–T_2 cancers of the oropharynx, larynx and hypopharynx.[7]

Transoral robotic surgery represents the most recent advance in minimally invasive head and neck oncological surgery. In just over a decade, it has transformed the management of upper aerodigestive tract malignancies, and has extended applications in benign pathologies.[8] It allows minimally invasive treatment to the upper aerodigestive tract because of significantly improved technology. In addition, telescopic three-dimensional visualisation means it can be used to operate on tumours that are not in the surgeon's direct line of sight. In contrast to laser surgery, transoral robotic surgery permits en bloc resection and, as a result, more effective evaluation of surgical margins.[9] By avoiding morbidities associated with open surgery – such as jaw split and tracheostomy – transoral robotic surgery is associated with shorter post-operative in-patient stays, the expedition of adjuvant therapies and lower costs.[10]

In patients with carcinoma of an unknown primary, transoral robotic surgery tongue base mucosectomy yields additional primary tumour detection rates of 50–90 per cent.[11–15] The increase of primary tumour detection rates minimises the morbidity of radiotherapy treatment to patients, as radiotherapy fields can be restricted to the involved oropharynx. Moreover, in some cases, contralateral neck treatment can be avoided if it is found that a tumour is lateralised to one side of the tongue base. Overall, detection of the primary tumour using transoral robotic surgery offers reduced morbidity from radiotherapy with or without

chemotherapy. These patients may also be eligible for entry into up-front transoral robotic surgery de-intensified adjuvant therapy trials, such as the Post-operative Adjuvant Treatment for HPV-positive Tumours ('PATHOS') trial.[16]

Transoral robotic surgery in carcinomas of an unknown primary is changing treatment paradigms. Use of transoral robotic surgery is now encompassed in a major multicentre study (PATHOS trial) that potentially could obviate the need for radiotherapy, resulting in a single-modality treatment, or, at least, limit the need for widespread irradiation of the aerodigestive tract which may lead to reduced toxicity. Interestingly, preliminary studies suggest that patients in whom the primary tumour has been detected by transoral robotic surgery will have better survival outcomes compared to those patients where no primary site has been identified.[3,17]

Understandably, there is great interest and enthusiasm for novel robotic surgery techniques such as transoral robotic surgery, but its introduction into the routine management of patients is a complex intervention, encompassing organisational, logistical and clinical challenges.[18] There are high costs associated with the necessary equipment – the latest model of the da Vinci robot costs around £1.7m and annual maintenance is estimated at £140 000.[19] Despite huge investments such as these, there have been reports of the underuse of robots in practice, making it very clear that the acquisition of a robotic surgery system alone is not enough for the successful implementation of transoral robotic surgery in the routine head and neck cancer service, especially in a challenging national healthcare system such as the National Health Service (NHS) in place in the UK.[20,21] In order to realise its benefits, the introduction of robotic surgery needs to address technological, organisational and social components – all of which can impact on patient outcomes.[18]

A standardised model for implementing a head and neck robotic surgery clinical programme within the UK's NHS has not been described. We present our experience of establishing such a programme in a UK tertiary head and neck cancer centre and of integrating it into routine management. In doing so, we identify lessons learned and provide a template for other centres wishing to establish a similar service. We also evaluate the programme by looking at the outcomes of 117 procedures undertaken since its inception.

Materials and methods

Practicalities of transoral robotic surgery

A systematic strategy was prepared over the course of three months in order to ensure that implementation and prospective evaluation of our transoral robotic surgery programme adhered to national and local governance requirements. This focused on the domains of: surgical team training, logistics, governance and multidisciplinary team (MDT) awareness.

Training

As a novel technique to our team, it was initially determined and agreed by the head and neck MDT that the existing practice had a sufficient target population to build up experience with the procedure. Initially, a small, dedicated team was established in order to ensure that adequate experience, confidence and skills were obtained, which could then be shared with a wider team. Efforts were made to ensure the regularity of participating personnel. The programme was led by a consultant who had carried out extensive work in pioneering the academic foundations of transoral robotic surgery in the UK. This knowledge was coupled with an international fellowship and course-based robotic surgery training. The lead surgeon acted as the console surgeon. A proctor was present in operating theatres for early cases, and an experienced head and neck surgeon initially acted as the bedside surgeon.

A series of essential steps were implemented, through acquisition of robotic surgery skills (accomplished by reviewing theoretical concepts and completing simulation training) and observation of cases.

The core team comprised all operating theatre staff who would be involved in subsequent transoral robotic surgery cases. A 'dry run' (rehearsal) was crucial in identifying potential problems, and helped establish confidence among the team.[8,18–20,22] The dry run was preceded by a team brief, included an emergency de-dock, and was followed by a trouble-shooting session and debrief. Furthermore, there were extensive discussions with our specialist histopathology team on preparing our standard operating procedures for transoral robotic surgery specimen inking, in an effort to facilitate accurate assessment of tumour dimensions and margins.

Logistics

The head and neck service initially benefited from close collaboration with urology surgeons. This team was already in possession of Da Vinci Xi robots (Intuitive, Sunnyvale, California, USA) and was able to provide adequate operating theatre access. The administrative team and managers were engaged in order to ensure that patients for whom robotic surgery was indicated could be prepared in time for available dates, to guarantee efficient use of this access.

We worked closely with Intuitive to ensure an adequate supply of instruments. In addition, we allocated additional time for cases in the beginning, in order to minimise time pressure.

Despite pressures from other specialties associated with competition for operating theatre time, regularity and frequency of procedures were crucial at this first stage of implementing robotic surgery systems in our practice. Therefore, Saturday operating lists were also utilised in order to maximise operating theatre capacity. During the first 12 months, transoral robotic surgery procedures were performed on an ad hoc basis on shared head and neck operating lists. This subsequently progressed to a dedicated head and neck transoral robotic surgery list.

Governance

The three-month pre-implementation planning phase involved submitting a proposal to our institution's Robotics Steering Committee in July 2017, which was approved the following month. We established protocols of peri-operative care, prepared patient information leaflets and arranged for the proctorship of early cases. A prospective evaluation of initial cases was established, and ethical approval submissions were made to our regional research ethics committee in preparation to join a multicentre study (the PATHOS trial).

Multidisciplinary team awareness

The oropharynx has considerable functional importance, and when it was the predominant site of transoral robotic surgery, several members of the head and neck team medics and associated healthcare professionals needed to work together to provide adequate support to patients. In addition to providing shared understanding and expertise of the transoral robotic

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surgery on the airway, anaesthetic colleagues were invaluable in preparing our post-operative pain protocol.

Speech and language therapists, physiotherapists, and nursing and oncology training staff were essential in supporting patients through recovery. Adjuvant therapy protocols were adapted as appropriate.

Having collaborated from the training phase of the project, we continued to work closely with our specialist head and neck pathology colleagues to ensure the accurate transmission of information from the operating theatre to the laboratory.[23] Standardised orientation of the specimens was implemented to ensure robust and reproducible margin assessment. Therefore, in addition to securing specimens to foam boards for orientation, the surgical team inked specimens in the operating theatre to ensure robust orientation. In addition, they shared surgical videos, where required, in order to better demonstrate specimen orientation.

Pre-operative planning (imaging)

Imaging has become integral to clinical staging, and is considered mandatory in the pre-operative investigation of head and neck cancer patients undergoing transoral robotic surgery. For oropharyngeal malignancies, magnetic resonance imaging (MRI) is the preferred modality owing to greater soft tissue contrast resolution and lower susceptibility to artefact from dental amalgam. Our institutional pre-operative imaging protocol includes axial T1- and T2-weighted turbo spin echo sequences, along with gadolinium-enhanced axial and coronal sequences (using the Dixon technique to achieve robust fat saturation). These anatomical sequences are supplemented by diffusion-weighted imaging, which aids in tumour delineation and differentiation from oedema.

Computed tomography (CT) is typically used second-line or where bone erosion is suspected. In cases of carcinoma of an unknown primary, MRI is typically supplemented by 18F fluorodeoxyglucose positron emission tomography (PET)/CT, as it has been shown to provide greater sensitivity when compared to conventional cross-sectional techniques in the search for an occult primary tumour.[24]

In our experience, routine use of MRI, interpreted by a dedicated head and neck radiologist, facilitates accurate staging and patient selection. In particular, it is capable of identifying tumoural features that may preclude transoral robotic surgery, such as: extension across the midline of the tongue, osseous and carotid involvement, or extension into masticator or prevertebral spaces.[25] It is also capable of identifying unfavourable features, such as invasion of adjacent structures or extensive nodal disease. Furthermore, imaging can be used to identify anatomical landmarks, as well as variants that might prove challenging intra-operatively, such as medialised carotid arteries or aberrant external carotid arterial branching. Collaborative working between the operating surgeon and radiologist can therefore help define tumour extent and resectability, and provide an anatomical roadmap for successful transoral robotic surgery.

Anaesthesia for transoral robotic surgery

Anaesthetic management of patients presenting for head and neck robotic surgery requires consideration for surgical and patient-specific requirements, and in particular an understanding of surgical access requirements and the degree of resection in the context of the patient's airway and other co-morbidities. All patients receive a standard pre-operative assessment, with particular focus on cardiorespiratory disease, the presence of obstructive sleep apnoea and airway assessment.

Obesity, the presence of obstructive sleep apnoea and intra-oral tumours may mandate advanced airway techniques in order to safely secure the airway. Intra-oral pathology may impede the ability to maintain facemask ventilation and obtain a view with direct laryngoscopy. Limited neck extension and mouth opening, and grade of laryngoscopy, may also predict the difficulty in obtaining good surgical access intra-operatively. Fibre-optic intubation of the trachea in the awake or anaesthetised patient may minimise trauma and tissue disruption at the site of pathology, or prevent multiple attempts at intubation.

Anaesthesia is often provided using total intravenous anaesthesia with neuromuscular paralysis, to ensure there is reduced risk of coughing with upper airway manipulation while the robot is docked. Remifentanil, used as strong, short-acting opioid, enables us to provide adequate up-titrated analgesia during a particularly stimulating period of suspension laryngoscopy. Other analgesics administered intra-operatively include longer-acting opioids such as fentanyl or morphine. Caution is exercised with large doses of opiates in the context of a safe extubation, particularly regarding obstructive sleep apnoea cases, long operative duration and significant surgical resection. Shared concerns regarding the post-operative airway may mandate a period of post-operative sedation and ventilation in intensive care, or tracheostomy.

Post-operative analgesia requirements vary with the degree of surgical resection, duration of surgery and pre-operative co-morbidities. We find a multi-modal analgesic approach beneficial, with regular use of paracetamol, anti-inflammatories and long-acting opiates into the early post-operative period. Re-education for staff within the patient pathway has been important in aiding understanding regarding the complexities of this surgical approach, and in emphasising that good analgesia is essential in the maintenance of swallow function.

Post-operative care

Head and neck ward trained nurses continue the care of transoral robotic surgery patients during the early post-operative period. Patients are encouraged to resume normal oral intake, and they are also assessed by speech and language therapists. In order to optimise their swallowing, strong analgesia and steroids are part of the post-operative medicines protocol. Rarely, patients might require nasogastric tube placement for nutrition.

Financing

A major limitation of robotic surgery systems is their cost. Therefore, each institution should consider the cost-effectiveness for the patient and the institution. As mentioned before, in our centre, robotic surgery was well established by our urology team colleagues. In the effort to optimise resources, while maintaining a cost-efficient robotic surgery service within our NHS Trust, a dedicated head and neck robotic surgery operating list was established.

The use of transoral robotic surgery generates new income through new diagnostic procedures. In carcinoma of an unknown primary presenting in the neck, transoral robotic surgery can be utilised for additional diagnostic procedures such as tongue base mucosectomy or tonsillectomy.

Looking forward, robotic surgery might avoid or decrease the costs of cancer treatments that involve six weeks of radiotherapy.[17,26] Unarguably, it reduces the length of stay in

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hospital and intensive care, as it involves less invasive procedures and, for example, avoids a mandible split.[27]

Patient selection and consent

The diagnostic pathway in our institution allowed early discussion with patients regarding the options of transoral robotic surgery diagnostic and therapeutic procedures. However, patients were formally given the choice between robotic-assisted surgery and conventional surgery or (chemo)radiotherapy following formal MDT meeting discussion. Informed consent was signed by all patients before surgery. Where relevant, patients involved in studies were consented by trained members of staff according to General Medical Council 'good clinical practice' and study protocols.

Prospective evaluation of early cases and auditing

Prospective data were collected on docking and console time, and complications. We included patient-reported outcome measures of pain, swallowing, voice and quality of life using validated assessment tools, in close collaboration with the Head and Neck Speech and Language and Dietetics team.

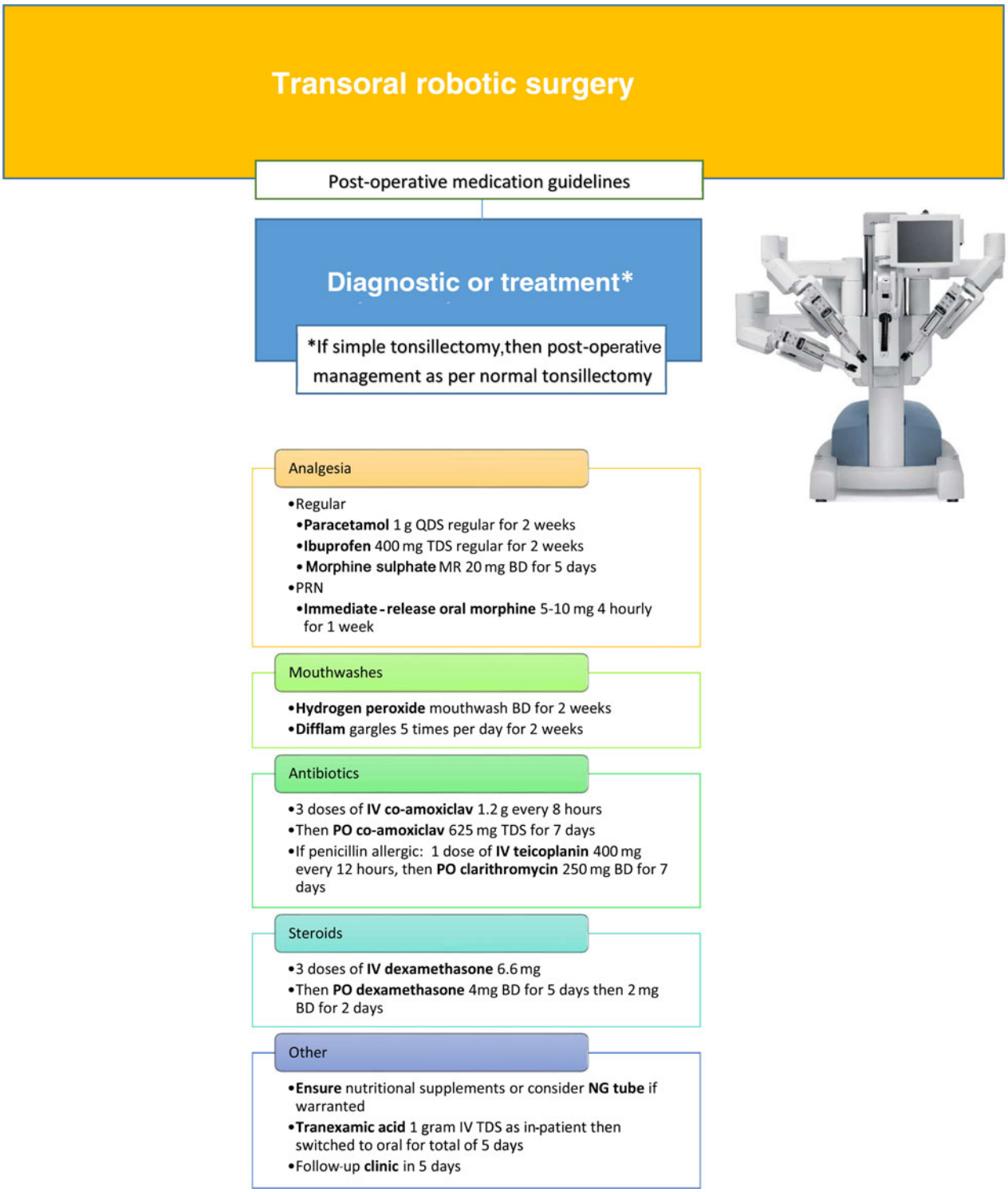

Fig. 1. Post-operative treatment protocol. QDS = four times daily; TDS = three times daily; MR = modified release; BD = twice daily; PRN = pro re nata (when required); IV = intravenous; PO = per oral; NG = nasogastric

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Table 1. Types of procedures performed

Type of procedure	First study period*	Second study period†	Total‡
Diagnostic tonsillectomy	12 (26.6)	20 (27.78)	32 (27.35)
CUP diagnosis**	12 (26.6)	21 (29.17)	33 (28.21)
Tonsil malignancy§	9 (20)	16 (22.22)	25 (21.37)
Posterior pharyngeal wall cancer	1 (2.22)	1 (1.39)	2 (1.71)
Parapharyngeal or retropharyngeal space disease	5 (11.11)	3 (4.17)	8 (6.84)
Epiglottis surgery	2 (4.44)	0 (0)	2 (1.71)
Tongue base lesion	4 (8.88)	9 (12.5)	13 (11.11)
Procedure abandoned	0 (0)	1 (1.39)	1 (0.85)
Missing data	0 (0)	1 (1.39)	1 (0.85)

Data represent numbers (and percentages) of cases. *$n = 45$; †$n = 72$; ‡$n = 117$. **Diagnostic investigations of an unknown primary tumour included bilateral tonsillectomy and tongue base mucosectomy. §Lateral oropharyngectomy. CUP = carcinoma of an unknown primary

Quantitative swallowing and pain scores are collected as routine (using the MD Anderson Dysphagia Inventory, and European Organisation for Research and Treatment of Cancer ('EORTC') quality of life questionnaire). The recordings were registered as an audit within the ENT/head and neck department in an effort to have standardised and official measure outcomes. Separate data were also collected for the PATHOS study for those relevant patients, while taking care not to duplicate questionnaire data when identical.

We classified our first 45 patients as early patients, and audited our results for them focusing on timings of the procedure, pain control, discharge time and re-admissions. Following evaluation with the anaesthetics consultants and the nursing team, it was agreed to implement changes in the transoral robotic surgery protocol in order to minimise aspects related to pain, time to discharge and re-admission. A detailed post-operative treatment protocol (Figure 1) was established and shared with the other members of the team who would care for the patient when on the ward. The most important change was that nasogastric tube insertion intra-operatively was considered essential only for major resections; most tubes are removed following enteral feeding after being reviewed by speech and language therapists.

Results

A total of 107 patients underwent 117 transoral robotic surgery procedures. During the first period (from January 2018 to June 2019), 45 procedures were recorded; during the second period (from July 2019 to December 2020), 72 procedures were performed. These procedures are summarised in Table 1.

Ten patients underwent two transoral robotic surgery procedures, seven unknown primary cases underwent a further procedure following diagnosis, two patients had positive margins and needed re-resection, and one patient underwent two diagnostic procedures for tongue base biopsy before and after treatment for a lymphoproliferative disease.

We defined carcinoma of an unknown primary as being clinically, radiologically and PET negative. In our cohort, we had 33 carcinomas of an unknown primary that were subsequently re-classified as: tonsillar tumours (12 cases, of which 1 was synchronous bilaterally), base of tongue tumours (9 cases), supraglottic tumours (2 cases) and glossotonsillar tumours (2 cases). The carcinoma remained unidentified in nine cases (Table 2).

Table 2. Location of primary tumour after diagnostic TORS for unknown primary tumours

Tumour subsite	Cases (*n* (%))*
Tonsil	12 (36.36)
Tongue base	9 (27.27)
Glossotonsillar sulcus	2 (6.06)
Supraglottis	2 (6.06)
Primary tumour remained unidentified	9 (27.27)

*Total $n = 33$. TORS = transoral robotic surgery

Docking and console time data were recorded for the first 45 cases. Mean docking time was 5.34 minutes (with docking time for the first three cases of 115, 12 and 10 minutes, respectively). Mean console time was 56.33 minutes, including all major resections, diagnostic procedures and tonsillectomies.

Three patients from the first period (6.67 per cent) and six patients from the second period (8.33 per cent) were re-admitted with post-operative bleeding.

Discussion

The success of the Guy's and St Thomas' Trust transoral robotic surgery programme is underpinned by a meticulous planning phase before the first procedure. Time was invested on creating awareness in the whole team of the new service implemented in our department. Several members of the team beyond main surgeons, such as senior head and neck fellows, senior anaesthetics consultants, and senior nurses, had attended international hands-on courses funded by the department, leading to an overall feeling of common ownership of the project. Multidisciplinary team awareness and governance support were crucial in order to minimise non-productive criticism within the department.

Dry rehearsals and cadaveric dissections were essential for the team to familiarise themselves with the technique before the first case, detecting issues such as correct placement of the robot within the operating theatre and safe driving towards the surgical table. During the initial phase, less complex cases were included, so becoming familiar with the technique was less challenging for the team members. At the end of the initial phase, docking times started to plateau. Five patients had complications in the early stage, while only one had complications in the later stage. The second phase included more complex cases such as oropharyngeal primary

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tumour resection, and parapharyngeal and retropharyngeal surgery. Over time, the team became more confident, such that, 16 months after our first case, we successfully performed our first dual-site robotic surgery jointly with thoracic surgeons.[28]

In 24 of the 33 transoral robotic surgery diagnostic procedures performed, the primary tumour site was identified. This had a major impact on management, as these patients were all enrolled in the PATHOS trial, and potentially could avoid chemotherapy or chemo-radiotherapy. There was no difference in primary tumour identification between the early and late phase of establishing the service, proving the value of the technique right from the beginning.

Although we acknowledge the limitations of this study, particularly the relatively small number of patients included compared to other international studies, the current paper highlights the challenges of establishing a new transoral robotic surgery service in a national healthcare system setting, and demonstrates how meticulous planning in a step-by-step approach can help to overcome these challenges.

- This is the first study standardising the implementation of a clinical head and neck robotic programme within the UK's National Health Service
- Programmes should encompass training, logistics, governance and multidisciplinary team awareness
- Consideration of pre-operative planning and imaging, anaesthesia, post-operative care, financing, and patient selection and consent are crucial
- Evaluation of early cases should be performed
- Detailed post-operative treatment protocols should be implemented

A planned, stepwise approach is important for units wishing to introduce a transoral robotic surgery service. Transoral robotic surgery has become internationally recognised as the new expected standard of management for certain oropharyngeal head and neck cancers.

Conclusion

Establishing a new transoral robotic surgery service in our department within the NHS, using a planned and stepwise approach, has, within three years, led to an established transoral robotic surgery protocol, the performance of more complex transoral resections, and participation in head and neck cancer trials such as the PATHOS trial. Currently, our main focus has moved to including transoral robotic surgery training in the advanced head and neck surgical oncology fellowship. We have also established several research projects in order to analyse our results and patient outcomes. In addition, we will explore the possibilities of improving the technology and changing the robot to a different model in the near future.

Competing interests. None declared

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