

Review

Robotic compared with open operations for cancers of the head and neck: a systematic review and meta-analysis

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Abstract

To compare the effectiveness and safety of robotic surgery with that of open operations for patients with cancers of the head and neck we made an electronic search of the CENTRAL, MEDLINE, EMBASE, CNKI, CBM, Opengray and Sciencepaper Online databases, and then made a manual search of specific online databases and the reference lists of relevant papers. Our most recent searches were made on 18 July 2018, and we included randomised controlled trials (RCT), case-control studies, cohort studies, and cross-sectional surveys in which robotic was compared with open surgery for cancer of the head and neck. Data from all the studies included were extracted by two independent workers. The risk ratio was chosen to measure dichotomous effects of treatment for prospective studies including RCT or cohort studies, while the odds ratio was chosen for case-control or cross-sectional studies. The weighted mean difference or standard mean difference was chosen to summarise continuous effects. A random-effects model was used for all data analyses. Thirteen studies were included: one RCT, nine cohort studies, and three cross-sectional studies. Robotic surgery was associated with fewer invaded resection margins, lower recurrence, less need for intraoperative tracheostomy, and less need and shorter duration of postoperative nasal feeding than open operations. Robotic surgery is a safe and feasible approach with remarkable superiority over open surgery for the treatment of cancers of the head and neck.

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Keywords: Head and neck cancers; Robotics; Minimally Invasive Surgical Procedures; Open Surgery

Introduction

Cancers of the head and neck refer to malignancies that occur on the oral cavity, sinuses, nasopharynx, oropharynx, larynx, or salivary glands. Nowadays they are considered to be the sixth most common cancers, and the ninth most common cause of death worldwide.¹ Their five-year survival

after diagnosis is 42%–64% in the developed world, and the one-year survival for advanced oral carcinoma is <50%.² Additionally they not only threaten a patient's life, but also have a great impact on the patient's appearance and physiological function. Some patients might develop severe sore throat, a hoarse-sounding voice, difficult or painful swallowing, and numbness or paralysis of the facial muscles. Nowadays, surgery remains the first line treatment for most head and neck cancers, but it can be particularly difficult because of the complexity of the anatomy and deficiency of tissues in the head and neck. Open surgery traditionally requires extensive open resection to obtain access to the posterior oral cavity and oropharynx, inevitably leaves a visible scar in the neck or chin, and results in considerable difficulty with speech and swallowing for most patients. This

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might also have a psychological impact on the quality of the patient's life. To aid in organ-preservation surgery, concurrent chemoradiation and endoscopic surgery have been increasingly used in the treatment of cancers of the head and neck, but they also have some deficiencies such as limited surgical view and toxic effects related to chemoradiotherapy, and they cannot ensure the preservation of an organ's function.

To overcome these deficiencies, transoral robotic surgery (TORS) was introduced as a minimally invasive surgical technique to provide non-invasive surgical exposure to the challenging area, with reduced morbidity.³ O'Malley et al⁴ proposed and used TORS for treatment of cancers of the base of tongue in 2006, since when many studies have shown the efficacy and safety of robotic surgery for T1-T4 cancers of the head and neck, including oropharyngeal cancer and those of the upper aerodigestive tract.^{5–8} In 2009 the use of the da Vinci surgical system (Intuitive Surgical, Inc) was approved by the US Food and Drug Administration (FDA) for the treatment of early stage oropharyngeal tumours (T1/T2).

As a new treatment for such cancers, robotic surgery showed advantages as well as disadvantages compared with traditional surgical techniques. The system could suppress physical tremors and provide a 3-dimensional magnified view of the patient's anatomy, allowing the surgeon to make precise movements. Several studies reported favourable oncological outcomes with TORS such as improved dexterity, decreased local tissue injury, and the subsequent requirement of microvascular reconstruction. The technique also minimises the morbidity associated with transcervical or lip-splitting mandibulotomy.^{9,10} However, the amount of time required by robotic surgery is much more than for traditional surgery, and some investigations have concluded that it might result in higher rates of some specific postoperative complications because of lack of haptic feedback.^{11–15}

In summary, the exact effectiveness and safety of this technique are still not clear. To acquire a comprehensive understanding of robotic surgery we organised this systematic review and meta-analysis, in which we attempted to evaluate the available evidence about different surgical approaches and their effects on the oncological efficacy, postoperative quality of life, and prognosis of the patients with neoplasms of the head and neck.

Methods

The protocol of this systematic review was previously developed and recorded in PROSPERO (CRD42016051495). It was organised in accordance with the instructions in the *Cochrane handbook for systematic reviews of interventions*¹⁶ and the PRISMA statement.¹⁷

Criteria for inclusion of studies

Studies were selected for inclusion independently and in duplicate by two reviewers. Any controversies were resolved by discussion with the third reviewer.

Types of studies: randomised controlled trials (RCT), case-control studies, cohort studies, and cross-sectional surveys in which robotic surgery was compared with open surgery were considered for inclusion. Case reports or case series were not included.

Types of participants: participants were chosen from among the patients who had been referred for treatment of head and neck neoplasms and, depending on the specific study, the following conditions were not considered for inclusion: chronic inflammation, salivary calculi, cleft lip and palate, jaw deformity, maxillofacial fracture, cystic lesion, thyroid tumour, oesophageal tumour, and other non-neoplastic diseases.

Types of interventions: robotic surgery using any surgical approaches for any resections of primary or recurrent head and neck neoplasm that was compared with open surgery for the same indications and follow-up was included. Robotic surgery compared with endoscopic surgery or chemoradiotherapy alone, robotic needle biopsy compared with traditional biopsy, and robotic radiotherapy compared with traditional radiotherapy or with other different robotic operations were not considered.

Types of outcome measures: eligible studies should report at least one of the following outcomes:

- 1 *Oncological outcomes:* rate of invaded margins, number of lymph nodes retrieved, survival, disease-free survival, and recurrence rate.
- 2 *Quality-of-life-related outcomes:* postoperative pain or paraesthesia, change in voice, swallowing, and cosmesis.
- 3 *Surgery associated measures:* duration of operation, operative blood loss, amount of drainage, and admissions to hospital.
- 4 *Complications:* hypoparathyroidism, bleeding, haematoma, seroma, infection, and chylous leak.

Search methods for identification of studies

The search for papers was made within MEDLINE, Embase, CENTRAL, CNKI, CBM, grey databases, and ongoing trials databases until July 2018, with languages restricted to English and Chinese. Grey databases such as Opengray and Sciencepaper Online were also retrieved. We also searched manually for relevant references from review articles and some specific journals. To find ongoing clinical trials, we searched the World Health Organization International Clinical Trials Registry Platform. When we constructed a retrieval formula, we combined MeSH-headings and free text words.

Collection and analysis of data

Selection of studies for inclusion: the title, key words, and abstract of all papers were first screened and checked according to the inclusion criteria. The full text was then reviewed and assessed for eligibility. The reviewers were aware of both the outcomes and the interventions.

Extraction and management of data: in addition to the main outcome measures, other descriptive data including: details of study (publication year, number of patients, type of study, and duration of follow up), baseline characteristics (age range, M:F ratio of participants, tumour size and stage, type of operation, and surgical approach of robotic surgery) and related interventions of interest were extracted from each study if available. Crude data were extracted if the adjusted results were not provided in an observational study.

Assessment of risk of bias: the Cochrane standard criteria were used for assessment of RCT, the Newcastle-Ottawa Scale was used for assessing the quality of cohort and case control studies, and the Agency for Healthcare Research and Quality (AHRQ) was used for assessment of cross-sectional surveys.

Analysis of data

The Cochrane Review Manager Software (RevMan, version: 5.3) was used for estimates of pooled effects. Because the bias varied among different study designs, separate meta-analyses were made. For dichotomous variables, the risk ratio (RR) using the Mantel-Haenszel test was chosen for prospective studies, otherwise odds ratio (OR) were chosen. For continuous variables, the weighted mean difference (WMD) using the inverse variance method was chosen as the measure if the pooled data were numerically similar and had the same unit - otherwise the standard mean difference (SMD) was chosen. All the results of the effects of treatment were presented using 95% CI, and probabilities of a significant difference were calculated at $\alpha = 0.05$.

Funnel plots were constructed to assess the publication bias for the comparison containing more than 10 studies, and then Egger's weighted liner regression test and the Harbord test were used for exact and quantitative examination using STATA MP Analytical Software (version 14, StataCorp) for continuous and dichotomous variables, respectively.

Investigation of heterogeneity: I^2 statistic (chi squared test) was used to assess heterogeneity using RevMan at the level of $\alpha = 0.10$. Subgroup analysis was made according to study design, intervention characters, or stage of tumour. A random-effects model was applied to all included studies because of low homogeneity among these studies.

Sensitivity analysis: a sensitivity analysis was made to evaluate the relative influence of each single study on the pooled outcomes by excluding them separately. Trim and fill analysis was then applied for sensitivity analysis if there was considerable publication bias. In addition, sensitivity analysis was not used for a meta-analysis containing fewer than three studies.

Data collection and analysis were made independently and in duplicate by two reviewers. Any controversies were resolved by discussion with the third reviewer.

Results

Table 1 gives a detailed description of the studies.

Results of the search

There were 1731 papers retrieved during the search and, after removing duplicates, 818 were left, including 10 ongoing studies and grey articles. After screening abstracts, 776 obviously irrelevant articles were excluded, which contained 78 thyroidectomy-related research papers. Forty-seven papers were then considered possibly eligible, and full texts were reviewed for further assessment. Other searching strategies failed to find any new articles, so after full text screening, 13 papers^{18–30} were included in the present review, while 29 research articles and five reviews were excluded (Fig. 1).

Characteristics of studies included

Thirteen studies that compared robotic resection of the upper airway and digestive tract by a transoral approach with open resection by a cervical or trans-mandibulotomy approach met the inclusion and exclusion criteria and were included in this review. These included one RCT,²² nine cohort studies,^{19–21,24–28,30} and three cross-sectional studies.^{18,23,29} Only two of the observational studies included multivariate logistic regression analysis or generalised linear regression analysis to adjust the surgery-related outcomes.^{18,29}

Risk of bias in the studies included

The only RCT contained no generation of random sequence or concealment of allocation, and participants and assessment of outcome were not concealed either. There was also a significant higher risk in attrition bias and relative unbalanced baseline (Supplemental Table 1).

All nine cohort studies showed sufficient representation of the treated cohort, and only one²⁴ did not select the non-exposed cohort from the same group with the exposed cohort. Four cohort studies controlled important confounding factors such as TNM stage, as well as some other inessential confounding factors such as sex, age, and body mass index. In contrast, three studies matched the most important confounding factor only, and in the other two cohort studies the baseline between the two cohorts was not balanced at all.^{19,24} All studies reported sufficient long-term follow up to assess outcome, and only one²⁴ reported a missing rate of more than 5% (Supplemental table 2).

Of the three cross-sectional studies included, none met all the criteria of the AHRQ assessment system (Supplemental table 3).

Table 1
Patient characteristics of included studies.

First author and reference	Patients					Site of resection	Intervention (transrobotic excision)	Control (open)	Outcomes	Follow up (months)	Study design
	No.	Mean (SD) age (years)		Sex (F/M)							
		Intervention	Control	Intervention	Control						
Richmon18	9601	-	-	33/83	2333/7152	Oropharynx	116	9485	c [‡] , e, f, g [†] , h	-	Cross-sectional
Dean ¹⁹	21	68 (5)	59 (11)	1/6	2/12	Oropharynx recurrent	7	14	c, d, e, f, g	6	Cohort
White ²⁰	128	61	61	16/48	11/53	Oropharynx recurrent	64	64	a, b, c, d, e, f, g, h, i	24	Cohort
Ford ²¹	130	59 (11)	58 (10)	13/52	14/51	Oropharynx	65	65	d, h, i	18	Cohort
Lee ²²	41	58 (9)	61 (8)	6/21	2/12	Oropharynx	27	14	a, c, d, f, g	60	RCT
Chung ²³	2067	59 (11)	59 (10)	122/401	215/714	Oropharynx	523	939	c, e, f, g	-	Cross-sectional
	894	57 (12)	60 (3)	26/121	27/720	Base of tongue	147	747	c, e, f, g	-	
	3983	60 (18)	60 (14)	19/49	754/3161	Anterior tongue	68	3915	c, e, f, g	-	
Morinière ²⁴	42	-	-	-	-	Upper aerodigestive tract	21	21	c, e, f, h	-	Cohort
Hammoudi ²⁵	52	61	62	8/18	8/18	Upper aerodigestive tract	26	26	a, c, d, e, f, g, h	Intervention n = 19; control n = 56	Cohort
Park ²⁶	56	67 (8)	63 (12)	0/30	1/25	Hypopharynx	30	26	a, b, c, d, e, f, g, h	21.4	Cohort
Park (a) ²⁷	34	66 (8)	66 (7)	1/16:	3/14	Supraglottis	17	17	a, c, d, e, f, g, h, i	-	Cohort
Biron ²⁸	47	60C	58	6/12	29	Oropharynx	18	29	a, c, d, f, g	12	Cohort
Motz ²⁹	3573	-	-	89/215	745/2523	Oropharynx	304	3268*	c [†] , e, f [‡] , g [†] , h	-	Cross-sectional
Slama ³⁰	49	-	-	5/17:	8/19	Oropharynx	22	27	b, h, i, j	34	Cohort

a = operative time; b = blood loss; c = hospital stay; d = margin status; e = tracheostomy rate; f = gastrostomy rate/feeding tube; g = complications; h = death rate/survival rate, i = recurrence; j = quality of life; - = not informed; * = other operation.

RCT: Randomised controlled study.

[†] adjusted through multivariate logistic regression analysis.

[‡] adjusted by generalised linear regression analysis.

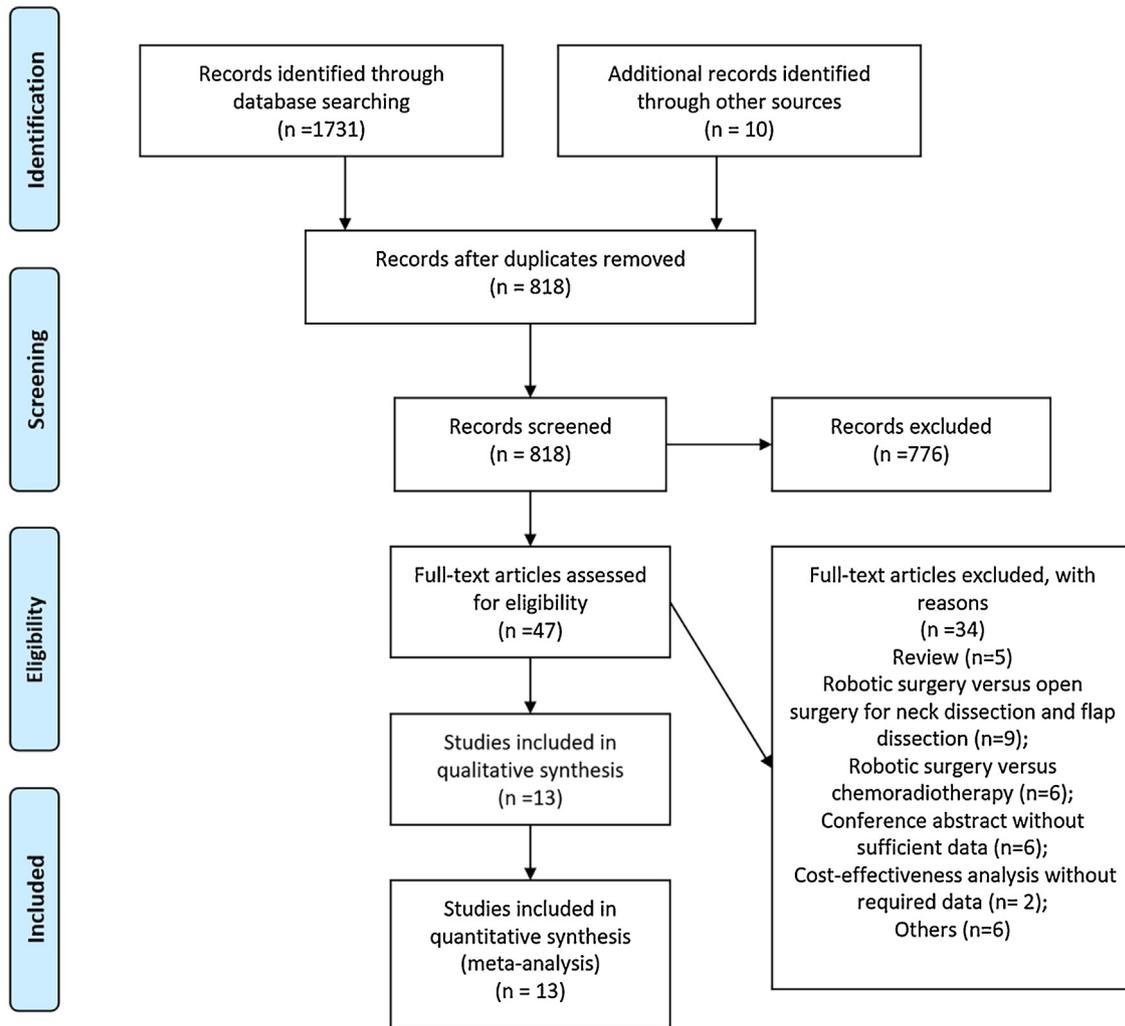


Fig. 1. Algorithm showing retrieval of papers.

Effects of interventions

Oncological outcomes

Status of margins: Seven cohort studies and one RCT reported the state of the incision margins, and only one study²⁰ reported a significant decrease in the number of invaded margins in robotic surgery, but the meta-analysis also showed that robotic surgery could significantly reduce the risk of invaded incision margins, particularly in the resection of oropharyngeal cancer (9.5% compared with 19.1%; RR 0.54 (95% CI 0.34 to 0.86; $p = 0.01$); $I^2 = 0\%$ (Fig. 2A). However, the sensitivity analysis showed that the deletion of the studies by Dean et al¹⁹ or White et al²⁰ would strongly affect the final result, indicating that the result was not reliable (data not shown).

Survival and recurrence rate: Data from six cohort studies were included in the meta-analysis, and the results showed that there was no difference between robotic and open surgery as far as death and disease-free survival were concerned (Fig. 2B), but robotic surgery seemed to reduce the recurrence rate significantly for resection of primary tumours

(8.3% compared with 17.8%; RR 0.48 (95% CI 0.25 to 0.91); $p = 0.02$; $I^2 = 0\%$) (Fig. 2C). White et al²⁰ reported a significant reduction in recurrence and death rate after robotic salvage surgery for recurrent oropharyngeal cancer.

No evidence of significant heterogeneity was detected, and the results were not sensitive to the exclusion of any single study in addition to the “recurrence rate for primary tumour resection”. The study by Ford et al²¹ seriously affected the combined result of recurrence and death rates (data not shown).

Quality-of-life-related outcomes

Assessment of impairment of swallowing: six cohort studies, two cross-sectional studies and one RCT evaluated the functional recovery of swallowing postoperatively by measuring the incidence and duration of gastrostomy or nasal feeding.

Gastrostomy: The result of the meta-analysis showed that there was no significant difference between robotic surgery and open surgery in the placement of a postoperative gastrostomy tube (Supplemental table 4). However,

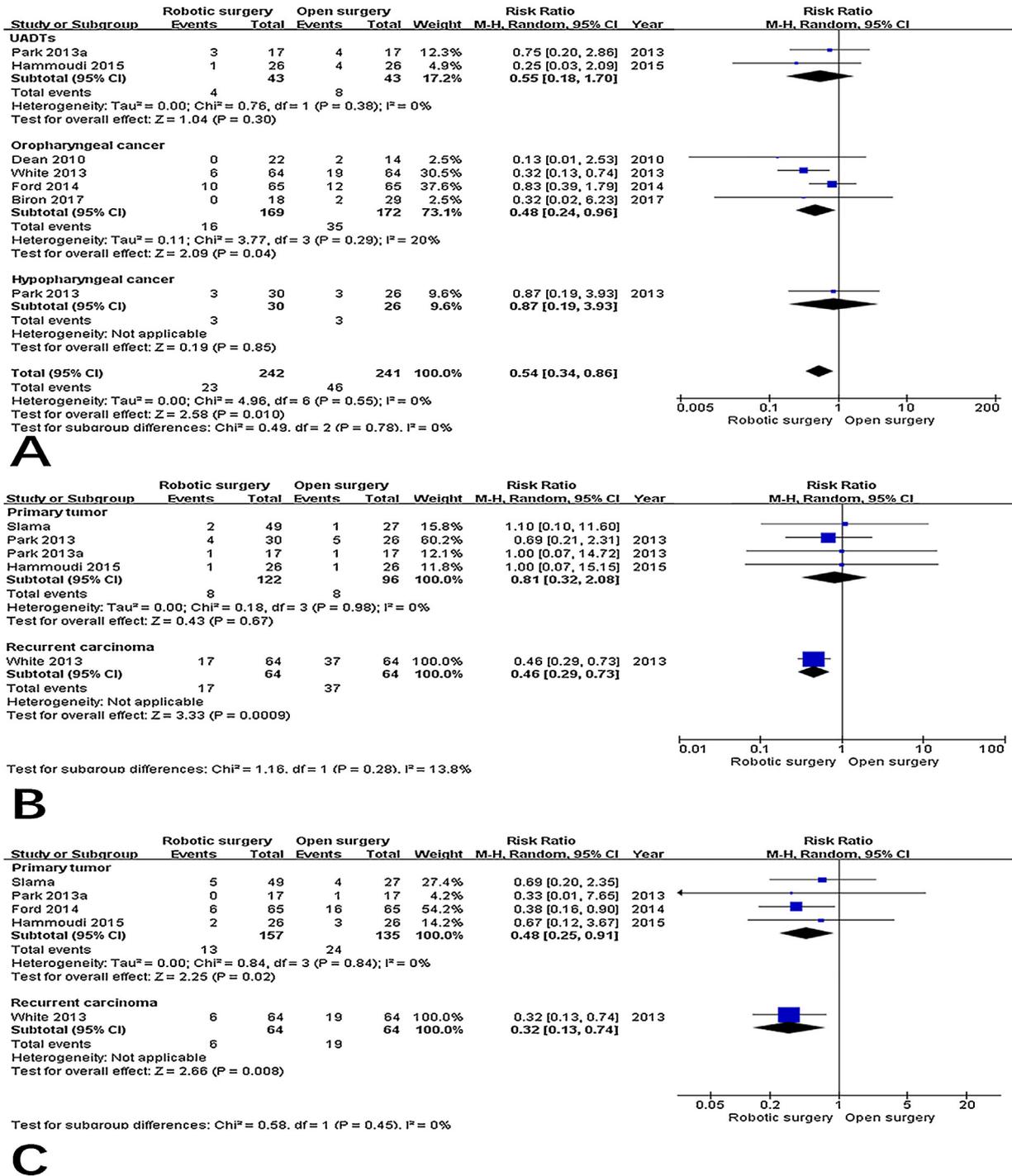


Fig. 2. Forest plot for robotic surgery compared with open operations for carcinomas of the upper aerodigestive tract, cohort study. A = status of margins; B = survival; and C = recurrences.

some investigations showed that robotic surgery might significantly increase the need for gastrostomy after resection of oral cancer,²³ but decrease the requirement after resection of oropharyngeal cancer.^{18,23}

Placement of a nasal feeding tube: The meta-analysis found that robotic surgery was associated with a significant lower requirement (44.4% compared with 82.2%; RR 0.57 (95% CI 0.41 to 0.81); p = 0.001; I² = 57%) and shorter

duration (WMD -9.75 [95% CI -11.80 to -7.70]; p < 0.0001; I² = 0%) of placement of a postoperative nasal feeding tube (Fig. 3A, B). The sensitivity of the results was not affected by the removal of any single study.

Surgery-associated measures

Duration of operation: data from five cohort studies and one RCT were included. Three of them^{22,26,27} showed a signif-

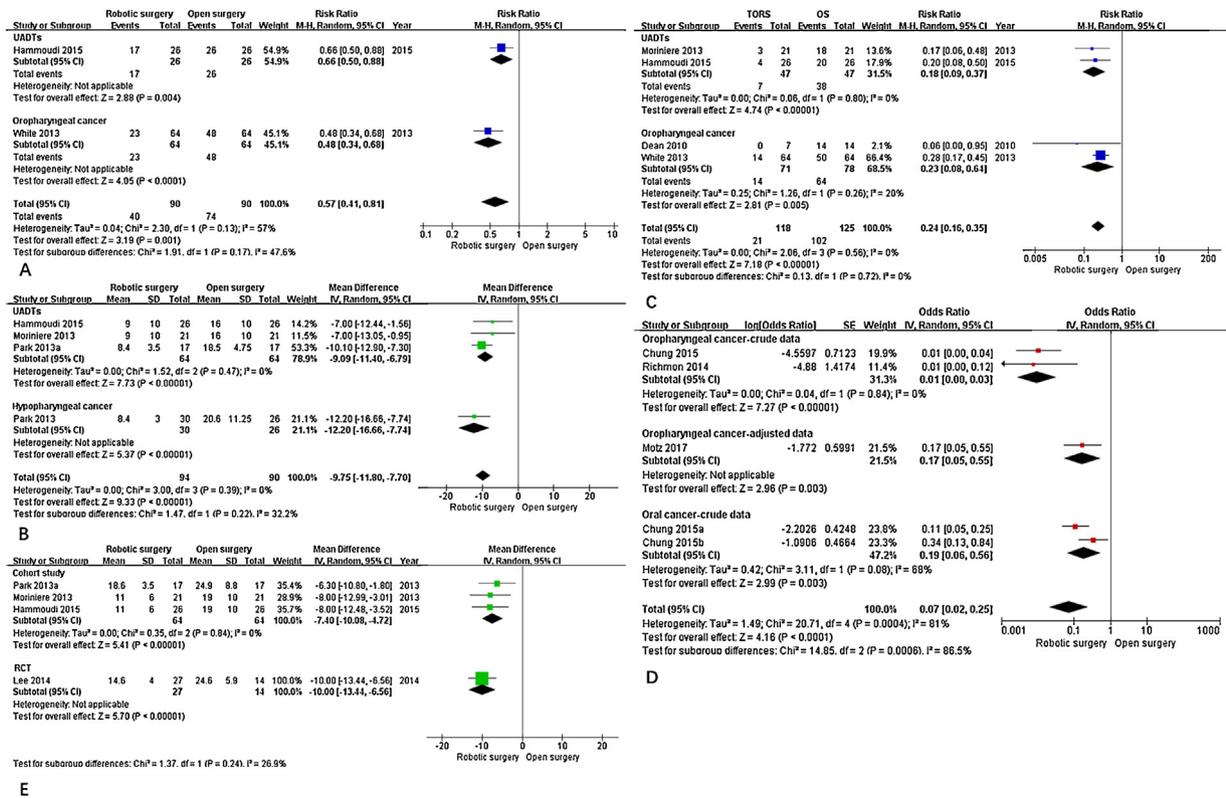


Fig. 3. Forest plot for robotic surgery compared with open operations for carcinomas of the upper aerodigestive tract. A = the requirement of postoperative placement of a nasal feeding tube, cohort study; B = the duration of placement of a postoperative nasal feeding tube, cohort study; C = the requirement of intraoperative tracheostomy, cohort study; D = the requirement of intraoperative tracheostomy, cross-sectional study; E = duration of stay in hospital.

icantly shorter duration of operation in the robotic surgery group, while the other three^{20,25,28} found no significant differences. We did not do a meta-analysis because of the limited number of studies and significant heterogeneity among those included.

Intraoperative tracheotomy: data from six cohort studies and three cross-sectional studies were included in this meta-analysis, in which two of them compared the duration of tracheotomy between robotic and open surgery, while eight compared the rates of intraoperative tracheotomy. The study by Chung et al²³ investigated three types of operation, including partial pharyngectomy for oropharyngeal cancer, partial glossectomy for cancer of the base of tongue, and partial glossectomy for the anterior tongue, so their data were divided into two parts (oropharyngeal cancer and oral cancer) and combined with other studies separately (Supplemental table 4).

The results showed that robotic surgery could significantly reduce the requirement for intraoperative tracheostomy (17.8% compared with 82.1%; RR 0.24 [95% CI 0.16 to 0.35]; P < 0.0001; I² = 0%) (Fig. 3 C and D), although the duration of tracheostomy was not significantly changed (Supplemental table 4). The results were not sensitive to the exclusion of any single study.

Blood loss: only three studies^{20,26,30} compared the intraoperative blood loss between the two groups, and both of them

showed that blood loss after robotic surgery was significantly lower for resections of oropharyngeal or hypopharyngeal cancer. However, data from these three studies could not be combined because some statistics (such as SD) were missing.

Hospital stay: seven cohort studies, one RCT, and one cross-sectional study, compared duration of hospital stay between robotic and open surgery, but four of them^{2,19,20,26} provided insufficient statistics (such as SD) for them to be included in this meta-analysis. This showed a significant reduction in hospital stay after robotic surgery (WMD -7.40 (95% CI -0.08 to -4.72); p < 0.0001; I² = 0%), and the results were not sensitive to the exclusion of any single study as well (Fig. 3E). In fact, among the included studies, only one study⁶³ reported a significantly longer hospital stay in the robotic group after partial glossectomy for an anterior tongue neoplasm.

Complications

We found no remarkable difference in the incidence of postoperative bleeding, oedema of the airway, fistula, infection, dysphagia, haematoma, and chyle leak between robotic and open surgery, although there was a lower risk of postoperative fistula and infection after robotic surgery (Supplemental table 4).

Discussion

Robotic surgery has been exponentially developing and widely applied in various head and neck operations since the FDA in the US approved it in late 2009. Although it seemed to make it easier to gain access to challenging anatomical sites such as the oropharynx, and with fewer complications, the introduction of any new technology is always going to be associated with potential challenges as well as advantages. Several studies have been reported that compare the effectiveness and safety of robotic and open surgery, and in this one we pooled the data from these studies that met our inclusion criteria to try and establish more certainty to provide clinical guidance for choosing the better treatment.

If we disregard the considerable time required for docking the robot and positioning the console, there is no remarkable difference in duration of operation, and three studies^{22,26,27} showed that robotic surgery was even quicker than transcervical open surgery, which might be attributed to the fact that TORS does not require an extended flap. The patients treated by TORS also seemed to have shorter hospital stays than those who had open operations.

With regard to intraoperative outcomes, the benefit obtained from the accurate dissection and 3-dimensional magnified visualisation of robotic surgery are significantly better for decreasing blood loss, reducing the requirement of intraoperative tracheostomy, and increasing the invaded margin rate compared with open surgery. As we know, the state of the resection margin is important in resections for cancer, and a clear margin is directly associated with better postoperative survival and lower recurrence.

Our results also showed that TORS may not improve disease-free survival or the overall survival rate two or five years after treatment, but could significantly reduce the recurrence rate compared with open surgery for either primary tumour resection or salvage operations.²⁰ TORS has also been reported to be associated with a trend for improved survival in HPV-negative patients with head and neck tumours, but without any clear explanation.²¹ As there has been a dramatic growth in HPV-induced head and neck tumours, and 50%–60% of oropharyngeal cancers are associated with HPV, HPV-negative patients were always thought to have a poorer prognosis.³¹ Although we do not have data to support the conclusion that TORS affords survival benefit in HPV-negative patients with oropharyngeal cancers, this possibility still deserves further investigation.

Assessment of the quality of life has always been one of the most important aspects of the evaluation of the efficacy of a new treatment for patients with head and neck cancer in addition to survival and recurrence rate. However, few of the studies that we included measured these outcomes, so there were insufficient data to provide solid evidence favouring any of the approaches. Several studies compared the requirement for gastrostomy or placement of a nasal feeding tube after resection and found no difference, but the duration of

placement of the nasal feeding tube was significantly shorter in the robotic group. In addition, traditional head and neck surgery through a transcervical or transmandibular approach was always associated with visible scars and even hypertrophic scarring. Robotic surgery could reduce the damage to surrounding normal tissues, and produce an invisible scar by using a remote or concealed incision, which could significantly improve the patients' cosmesis and result in better postoperative quality of life.

For postoperative complications, there were no significant differences in the incidence of postoperative complications between robotic and open surgery. However, our meta-analysis found that the robotic approach might reduce the risk of wound infection and pharyngocutaneous fistula, probably because of the minimised pharyngeal defect and less requirement for intraoperative microvascular flap reconstruction.²⁶ It must be noted that robotic surgery gives absolutely different surgical accesses from open surgery, so we did find some newly-introduced complications (such as numbness of the earlobe) after trans-postauricular robotic surgery. Marginal nerve palsy was also reported more often during robotic surgery, which may have been caused by compression damage by the robot arm or thermal injury from the harmonic shears. Improvement in design of the incision and the reality of haptic feedback during robotic surgery are therefore urgently required.

Some other studies^{32–34} compared TORS alone with TORS plus adjuvant radiotherapy, and the results showed that adjuvant radiotherapy would significantly diminish postoperative functional recovery and long-term quality of life with comparable or even worse oncological outcomes to TORS alone, particularly in patients with early-stage cancers. This might be associated with higher systematic toxicity and saliva-related damage of chemoradiotherapy, and so the justification for robotic surgery could be a reduction in toxicity from a reduced dose of radiation and possible elimination of adjuvant chemotherapy.

Although our study could provide helpful references for clinical decision-making and the development of robotic surgery, there were two major limitations that need to concern us. On the one hand, a valid conclusion on long-term oncological outcomes could not be drawn from limited investigations, and further studies with low risks of bias are required to provide solid evidence. On the other hand, the quality of most of the studies included was good enough, and only two of the observational studies reported multivariate logistic regression or generalised linear regression. However, most of these studies controlled the potential confounding factors including HPV status, age, smoking, TNM stage, and adjuvant chemoradiotherapy.

Conclusions

According to the studies included and our results, we conclude that the robotic surgical system has remarkable benefits

in reducing the rate of invaded margins, decreasing complications, and improving patients' quality of life compared with conventional open surgery for head and neck cancer. However, the lack of haptic feedback and its high cost may be the major limitations so far. Only a few studies investigated the oncological outcomes as well as the long-term functional recovery and quality of life, so there is still a long development period for robotic surgery before it becomes a universal treatment. Until the above-mentioned uncertainties are settled, further well-designed studies aimed at these core issues are urgently needed.

Ethics statement/confirmation of patients' permission

Not necessary.

Conflict of interest

We have no conflicts of interest.

Acknowledgements

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.bjoms.2019.08.023>.

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