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Type of anastomosis and risk of anastomotic insufficiency after oesophagectomy: a bi-national population-based cohort study

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ABSTRACT

Background: It is uncertain which type of anastomosis carries the lowest risk of anastomotic insufficiency after oesophagectomy for oesophageal cancer. We aimed to compare handsewn with stapled anastomosis (any type, linear or circular), and handsewn end-to-side with handsewn end-to-end anastomosis.

Methods: This bi-national population-based cohort study included almost all patients (>95 %) who underwent oesophagectomy for cancer in Sweden from 2011 to 2020 or in Finland from 2004 to 2016. Multivariable logistic regression produced odds ratios (OR) with 95 % confidence intervals (CI), adjusted for age, sex, comorbidity, tumour histology, neoadjuvant chemo(radio)therapy, surgical approach, anastomosis location, hospital volume, and pathological tumour stage.

Results: Among 2166 study patients, 327 (15 %) had anastomotic insufficiency. The risk of anastomotic insufficiency was borderline significantly decreased in handsewn anastomosis compared to stapled anastomosis (OR = 0.79, 95 % CI 0.60–1.05). In patients who underwent minimally invasive oesophagectomy, handsewn anastomosis was associated with a decreased risk compared to stapled anastomosis (OR = 0.55, 95 % CI 0.35–0.85; n = 999), while no such association was found after open oesophagectomy (OR = 1.04, 95 % CI 0.72–1.51; n = 1167). There were no statistically significant associations with anastomotic insufficiency when comparing linear stapled with circular stapled anastomosis (OR = 1.27, 95 % CI 0.70–2.28; n = 736) or handsewn with circular stapled anastomosis (OR = 0.94, 95 % CI 0.63–1.40; n = 1324). Handsewn end-to-side anastomosis was associated with a borderline increased risk of anastomotic insufficiency compared to handsewn end-to-end anastomosis (OR = 1.61, 95 % CI 0.93–2.78; n = 786).

Conclusions: Regarding anastomotic insufficiency, handsewn anastomosis may be favourable compared to stapled in minimally invasive oesophagectomy for oesophageal cancer, while no such benefit was found for open oesophagectomy.

1. Introduction

Oesophageal cancer is the 7th most common cause of cancer-related deaths and the 11th most common cancer worldwide [1]. Its 5-year survival rate is less than 20 % [2]. The mainstay of curative treatment is oesophagectomy (open or minimally invasive) using a gastric tube as the conduit and is often combined with chemo(radio)therapy [3]. The surgery is extensive and followed by a high rate of complications [4]. Anastomotic insufficiency is among the most feared complications, which occurs in 13–34 % of patients [5–7]. Anastomotic insufficiency can cause serious postoperative morbidity, long-lasting reduction in health-related quality of life, and increased short- and long-term mortality [8,9]. Risk factors for anastomotic insufficiency include comorbidity, long operating time [8], minimally invasive surgery [10], hypoproteinaemia, and squamous cell carcinoma histology [11]. The anastomosis is constructed with a handsewn or stapled (linear or

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circular) technique and with end-to-side, end-to-end, or side-to-side anatomy [12]. The technique correlates with the anatomy, i.e., circular stapled anastomosis usually generates an end-to-side anastomosis, linear stapled anastomosis generates a side-to-side anastomosis, and handsewn anastomosis generates either an end-to-end or an end-to-side anastomosis [13,14]. The literature is inconsistent regarding which type of anastomosis is preferable to construct in terms of risk of anastomotic insufficiency. Most studies suggest that stapled anastomosis is advantageous over handsewn anastomosis in this respect [15,16], but the studies suffer from small sample sizes and methodological issues. Fewer studies have been conducted to determine whether anastomotic anatomy affects the likelihood of anastomotic insufficiency. Handsewn end-to-end anastomosis and handsewn end-to-side anastomosis have been compared but with conflicting results [14,17]. Using a bi-national cohort design, this study aimed to examine the hypotheses that the risk of anastomotic insufficiency following surgery for oesophageal cancer is higher after handsewn compared to stapled anastomosis and is similar between handsewn end-to-side and handsewn end-to-end anastomosis.

2. Methods

2.1. Study design

This was a population-based cohort study including almost all patients having undergone curatively intended oesophagectomy for oesophageal cancer between 2011 and 2020 in Sweden or between 2004 and 2016 in Finland. We compared anastomotic techniques and anastomotic anatomies in relation to the risk of anastomotic insufficiency. Ethical permissions were obtained from the regional ethical review boards in Stockholm, Sweden, and Oulu, Finland.

2.2. Data sources

Data came from two nationwide and well-established cohorts. The Swedish Oesophageal Cancer Surgery Study (SESS) includes patients having undergone oesophagectomy for oesophageal cancer in Sweden from year 1987 until end of year 2020. For this study, we included patients who had undergone oesophagectomy from 2011, due to the high frequency of missing data on type of anastomosis before 2011. The Finnish National Esophago-Gastric Cancer Cohort (FINEGO) includes patients with oesophageal cancer in Finland from year 1987 until end of 2016. For this study, we included patients having undergone oesophagectomy from 2004 because stapled anastomosis was uncommon in Finland before 2004. These cohorts have been combined and described elsewhere [18,19]. In brief, individuals with oesophageal cancer were identified in the national cancer registries, and information about oesophagectomy and comorbidity was retrieved from the national patient registries in Sweden and Finland. Medical records were collected and reviewed for all patients to provide detailed clinical information, including technique, anatomy and location of the anastomosis, as well as histological subtype, neoadjuvant chemo(radio)therapy, hospital volume of oesophagectomy, surgical approach, pathological tumour stage, and complications, including anastomotic insufficiency. These cohorts combined include >95 % of all patients having undergone oesophagectomy for oesophageal cancer in Sweden or Finland during the study period [18,19].

2.3. Exposures

Four exposures were assessed. 1) The main exposure was any type of handsewn anastomosis versus any type of stapled anastomosis (reference group). Secondary exposures were: 2) handsewn anastomosis versus circular stapled anastomosis (reference group), 3) linear stapled anastomosis versus circular stapled anastomosis (reference group), and 4) handsewn end-to-side anastomosis versus handsewn end-to-end anastomosis (reference group). We did not examine side-to-side anastomosis because of its rarity in handsewn anastomosis. Cross-tabulation conducted before the analysis showed that circular stapled anastomosis strongly correlated with end-to-side anastomosis and that linear stapled anastomosis strongly correlated with side-to-side anastomosis. As a result, these anatomies were not studied.

2.4. Outcome

The outcome was anastomotic insufficiency, defined as insufficiency objectively verified by computer tomography or gastroscopy, which were done whenever clinical signs or patient symptoms of such insufficiency appeared after the oesophagectomy.

2.5. Statistical analysis

We did not make any sampling, but included all eligible patients in Sweden and Finland, making sample size calculations irrelevant. Associations between type of anastomosis and anastomotic insufficiency were estimated using multivariable logistic regression, which produced odds ratios (OR) with 95 % confidence intervals (CI). A crude model did not adjust for any confounders. A main model adjusted for the following nine possible confounders, with categorization in brackets: Age (continuous) [20], sex (male or female) [21], comorbidity (score 0, 1 or ≥2 according to the Charlson Comorbidity Index, based on comorbidities recorded up to 6 years before the oesophagectomy) [8,22], tumour histology (adenocarcinoma or squamous cell carcinoma) [21], neoadjuvant chemo(radio)therapy (yes or no) [23], surgical approach (open or minimally invasive) [10,24], anastomosis location (cervical or intrathoracic) [5], hospital volume of oesophagectomy (using a 4-year moving average annual number of oesophagectomies for each hospital, which included the hospital volume for year of surgery and 3 years prior for each patient) [25], and pathological tumour stage (0-I, II, or III-IV according to the 8th edition of the American Joint Committee on Cancer/the International Union Against Cancer) [26]. We also evaluated six potential effect modifiers, i.e., calendar year (above and below the median value), country (Sweden and Finland), surgical approach (open and minimally invasive), anastomosis location (cervical and intrathoracic), neoadjuvant chemo(radio)therapy (yes and no), and hospital oesophagectomy volume (above and below the median value). An interaction term was included for the type of anastomosis for the main exposure and each potential effect modifier in the main multivariable model one by one, with ORs derived within each stratum. We used complete case analysis because the proportion of missing data for confounders was low. The statistical analyses were conducted using the statistical software Stata/IC 14.0 (StataCorp LLC). All data management and analyses followed a predefined study protocol.

3. Results

3.1. Patients

The source cohort included 2326 patients having undergone oesophagectomy for oesophageal cancer during the study period. We excluded patients who had non-elective surgery (n = 6), surgery without curative intention (n = 24), no information on type of anastomosis (n = 36) or anastomotic insufficiency (n = 6), and missing data on any of the confounders (n = 88). The excluded patients were evenly distributed between patients with stapled anastomosis and handsewn anastomosis. After these exclusions (n = 160), 2166 patients remained for final analysis. Of these participants, 1301 (60 %) had a stapled anastomosis and 865 (40 %) had a handsewn anastomosis. Patient characteristics are presented in Table 1a. The groups with stapled and handsewn anastomosis had a similar distribution of age, sex, and comorbidity. Stapled anastomosis was more common in Sweden than Finland and in the minimally invasive approach compared to the open approach. The proportion of intrathoracic anastomosis was higher in the stapled

Table 1
a. Characteristics of 2166 study patients who underwent oesophagectomy for oesophageal cancer in Sweden or Finland, grouped by anastomotic technique.

Patient characteristics	Stapled anastomosis Number (%)	Handsewn anastomosis Number (%)
Total	1301 (60.1)	865 (39.9)
Country		
Sweden	908 (69.8)	517 (59.8)
Finland	393 (30.2)	348 (40.2)
Age, median (interquartile range)	67.5 (61.0–73.4)	66.8 (59.5–72.0)
Sex		
Women	260 (20.0)	196 (22.7)
Men	1041 (80.0)	669 (77.3)
Charlson comorbidity score		
0	887 (68.2)	598 (69.1)
1	262 (20.1)	189 (21.9)
≥2	152 (11.7)	78 (9.0)
Tumour histology		
Adenocarcinoma	1092 (83.9)	632 (73.1)
Squamous cell carcinoma	209 (16.1)	233 (26.9)
Neoadjuvant therapy		
Yes	890 (68.4)	551 (63.7)
No	411 (31.6)	314 (36.3)
Surgical approach		
Open	539 (41.4)	628 (72.6)
Minimally invasive	762 (58.6)	237 (27.4)
Anastomosis location		
Cervical	130 (10.0)	355 (41.0)
Intrathoracic	1171 (90.0)	510 (59.0)
Hospital volume of oesophagectomy, median (interquartile range)	32.5 (17.0–39.3)	20.5 (13.3–36.8)
Pathological tumour stage		
0-I	443 (34.1)	339 (39.2)
II	220 (16.9)	139 (16.1)
III-IV	638 (49.0)	387 (44.7)
Anastomotic insufficiency		
Yes	210 (16.1)	117 (13.5)
No	1091 (83.9)	748 (86.5)

anastomosis group. Patients with stapled anastomosis more commonly had adenocarcinoma histology and somewhat more advanced pathological tumour stage than those with handsewn anastomosis. Stapled anastomosis was more common in hospitals with a higher annual volume of oesophagectomy and somewhat more common in patients who received neoadjuvant treatment (Table 1a).

In supplementary table Table 1b, patient characteristics are grouped by the occurrence of anastomotic insufficiency or not. The groups had a similar distribution of most characteristics, but anastomotic insufficiency was more common in Sweden than Finland, and after minimally invasive surgery compared to open surgery. Patients with higher comorbidity had a higher frequency of anastomotic insufficiency, and insufficiency was slightly more common in cervical anastomosis compared to the intrathoracic location (Table 1b).

3.2. *Risk of anastomotic insufficiency*

The overall anastomotic insufficiency rate was 15.1 % (n = 327), and 16.1 % in the group with a stapled anastomosis and 13.5 % among those with a handsewn anastomosis.

The analysis of all patients showed a borderline significant decreased risk of anastomotic insufficiency in handsewn anastomosis compared to stapled anastomosis (adjusted OR 0.79, 95 % CI 0.60–1.05). In patients who had the open approach, no association was found comparing handsewn with stapled anastomosis (adjusted OR 1.04, 95 % CI 0.72–1.51), whereas in patients who underwent the minimally invasive approach, handsewn anastomosis was associated with a decreased risk of anastomotic insufficiency compared to stapled anastomosis (adjusted OR 0.55, 95 % CI 0.35–0.85). In the separate analyses of patients in different calendar year periods, from Sweden and Finland, with and without neoadjuvant therapy, cervical and intrathoracic location, or different categories of annual hospital volume of oesophagectomy, there were no statistically significant associations between handsewn and stapled anastomosis and risk of anastomotic insufficiency. (Table 2).

No statistically significant associations were found regarding the risk of anastomotic insufficiency when comparing linear stapled anastomosis with circular stapled anastomosis (OR 1.27, 95 % CI 0.70–2.28), or handsewn anastomosis with circular stapled anastomosis (OR 0.94, 95 % CI 0.63–1.40) (Table 3). Handsewn end-to-side anastomosis was associated with a borderline significant increased risk of anastomotic insufficiency compared to handsewn end-to-end anastomosis (adjusted OR 1.61, 95 % CI 0.93–2.78) (Table 4).

4. Discussion

This study found no support for the hypothesis that handsewn anastomosis is associated with a higher risk of anastomotic insufficiency than stapled anastomosis after oesophagectomy for oesophageal cancer. After minimally invasive surgery, handsewn anastomosis was instead associated with a decreased risk of anastomotic insufficiency compared to stapled anastomosis, while no association was found after open oesophagectomy. No clear associations with anastomotic insufficiency were found when comparing linear stapled anastomosis and handsewn anastomosis with circular stapled anastomosis. The results are suggestive of an increased risk of anastomotic insufficiency after handsewn end-to-side anastomosis compared to handsewn end-to-end anastomosis.

A major strength of the study is its population-based design, which included nearly all patients in two entire countries. This created a sizable study population, mitigated selection bias, and made the findings more generalizable. Other strengths include the richness of data from medical records and high-quality registries, enabling adjustment for several confounders. Among weaknesses is still that the observational design cannot rule out residual or unknown confounding. The limited incidence of anastomotic insufficiency reduced the statistical power, but this research represents the largest study on the subject to date. There was no information on salvage oesophagectomy, which can increase the risk of anastomotic insufficiency [27]. However, this should not be a major concern in the present study because the rate of salvage surgery in oesophageal cancer is low in Sweden and Finland, and both handsewn and stapled anastomosis are used in salvage oesophagectomy.

Table 2
Risk of anastomotic insufficiency comparing handsewn with stapled anastomosis in 2166 patients who underwent oesophagectomy for oesophageal cancer.

	Patients	Stapled anastomosis	Handsewn anastomosis
	Number	Odds ratio (95 % confidence interval)	
Crude model	2166	1.0 (reference)	0.81 (0.64–1.04)
Main model[a]	2166	1.0 (reference)	0.79 (0.60–1.05)
Stratified analyses[a]			
Calendar year ≥ median	1213	1.0 (reference)	0.71 (0.50–1.02)
Calendar year < median	953	1.0 (reference)	1.07 (0.69–1.67)
Sweden	1425	1.0 (reference)	0.88 (0.65–1.19)
Finland	741	1.0 (reference)	1.08 (0.66–1.79)
Neoadjuvant therapy	1441	1.0 (reference)	0.73 (0.52–1.03)
No neoadjuvant therapy	725	1.0 (reference)	0.91 (0.59–1.42)
Open surgery	1167	1.0 (reference)	1.04 (0.72–1.51)
Minimally invasive surgery	999	1.0 (reference)	0.55 (0.35–0.85)
Cervical anastomosis	485	1.0 (reference)	0.70 (0.42–1.16)
Thoracic anastomosis	1681	1.0 (reference)	0.83 (0.60–1.16)
Hospital volume ≥ median	1099	1.0 (reference)	0.84 (0.55–1.27)
Hospital volume < median	1067	1.0 (reference)	0.83 (0.57–1.21)

[a] Adjusted for age, sex, comorbidity, tumour histology, neoadjuvant chemo (radio)therapy, surgical approach, anastomosis location, hospital volume of oesophagectomy, and pathological tumour stage.

Table 3
Risk of anastomotic insufficiency comparing linear stapled anastomosis and handsewn anastomosis with circular stapled anastomosis in 1433 patients who underwent oesophagectomy for oesophageal cancer.

	Patients	Circular stapled (n = 627)	Linear stapled (n = 109)	Handsewn (n = 697)
	Number	Odds ratio (95 % confidence interval)		
Crude model	1433	1.0 (reference)	1.58 (0.91–2.74)	1.05 (0.76–1.47)
Main model[a]	1433	1.0 (reference)	1.27 (0.70–2.28)	0.94 (0.63–1.40)

[a] Adjusted for age, sex, comorbidity, tumour histology, neoadjuvant chemo(radio)therapy, surgical approach, anastomosis location, hospital volume of oesophagectomy, and pathological tumour stage.

Table 4
Risk of anastomotic insufficiency comparing handsewn end-to-side anastomosis with handsewn end-to-end anastomosis in 786 patients who underwent oesophagectomy for oesophageal cancer.

	Patients	Handsewn end-to-end anastomosis (n = 318)	Handsewn end-to-side anastomosis (n = 468)
	Number	Odds ratio (95 % confidence interval)	
Crude model	786	1.0 (reference)	1.74 (1.11–2.72)
Main model[a]	786	1.0 (reference)	1.61 (0.93–2.78)

[a] Adjusted for age, sex, comorbidity, tumour histology, neoadjuvant chemo (radio)therapy, surgical approach, anastomosis location, hospital volume of oesophagectomy, and pathological tumour stage.

This is the first study comparing handsewn and stapled anastomosis regarding the risk of anastomotic insufficiency after minimally invasive oesophagectomy. The results favoured handsewn anastomosis. Studies have reported a relatively low incidence (2–9 %) of anastomotic insufficiency after minimally invasive oesophagectomy [28–30], but these estimates are difficult to interpret without a comparison group. There are challenges with creating a handsewn anastomosis using the minimally invasive approach, although hand-sewing may be a more controlled process [16]. The decreased risk of anastomotic insufficiency after handsewn anastomosis found in the present study could potentially be attributed to the preference of more experienced surgeons for handsewn anastomosis. It is not known whether the choice of technique was influenced by availability, preference, or necessity. Availability of equipment could for example influence the choice. However, during the study period, both handsewn and stapled techniques have been widely available in both countries. In minimally invasive surgery, or when creating a cervical anastomosis, the choice may be made out of necessity, but because the results are adjusted for these variables, the risk for confounding is low.

The lack of association between handsewn and stapled anastomosis after open oesophagectomy is in contrast to a meta-analysis of 17 studies of various designs and a total of 2123 patients, which suggested a 2-fold increased risk of anastomotic insufficiency in patients with handsewn anastomosis compared to stapled anastomosis (OR 2.02, 95 % CI 1.48–2.75) [15]. However, the definition of anastomotic insufficiency was not consistent, introducing heterogeneity and bias. The finding of the present study is in line with the findings of another meta-analysis of 6 randomized controlled trials and 1454 patients (relative risk 0.92, 95 % CI 0.45–1.87, comparing stapled with handsewn anastomosis) [31], as well as two earlier meta-analyses of randomized controlled trials [32, 33]. However, during the wide study periods in these meta-analyses, the surgical and medical treatment of oesophageal cancer has changed substantially, introducing heterogeneity.

No difference in risk of anastomotic insufficiency was revealed when comparing handsewn with circular stapled anastomosis, which is supported by two meta-analyses of randomized controlled trials [34,35]. Linear stapled anastomosis showed a similar risk of anastomotic insufficiency compared to circular stapled in this study, while in a recent meta-analysis, linear stapled anastomosis was associated with a decreased risk of anastomotic insufficiency compared to circular stapled anastomosis [36]. A recent meta-analysis, comprising 101 studies and 12 595 patients, indicated that handsewn and linear stapled anastomosis were associated with higher risk of anastomotic insufficiency compared to circular stapled anastomosis [37]. But rather than comparing the anastomotic types directly, the majority of the included studies made comparisons on an aggregate basis, which runs the risk of introducing bias and heterogeneity.

In this study, handsewn end-to-side anastomosis was associated with a seemingly increased risk of anastomotic insufficiency compared to handsewn end-to-end anastomosis. This finding is supported by a randomized controlled trial of 128 patients [17]. However, a cohort study of 252 patients showed no difference in anastomotic insufficiency rate between handsewn end-to-end and end-to-side anastomosis after minimally invasive oesophagectomy [14].

Large randomized controlled trials comparing handsewn and stapled anastomosis in minimally invasive oesophagectomy in relation to the risk of anastomotic insufficiency are warranted. More research is also needed to clarify whether circular or linear stapled anastomosis is favourable regarding risk of anastomotic insufficiency, and to provide clarity on whether end-to-end or end-to-side is the best option for handsewn anastomosis.

In conclusion, this large and population-based cohort study with adjustment for relevant confounders suggests that handsewn anastomosis and stapled anastomosis are followed by a similar risk of anastomotic insufficiency after open oesophagectomy for oesophageal cancer, whereas handsewn anastomosis may be preferable over stapled anastomosis in minimally invasive oesophagectomy. The risk of anastomotic insufficiency may not differ when comparing linear stapled anastomosis and handsewn anastomosis with circular stapled anastomosis, but handsewn end-to-side anastomosis may be associated with an increased risk compared to handsewn end-to-end anastomosis.

CRediT authorship contribution statement

Ellen Jonson: Conceptualization, Methodology, Software, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization, Project administration. **Eivind Gottlieb-Vedi:** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Writing – review & editing. **Fredrik Mattsson:** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Emilia Putila:** Investigation, Resources, Writing – review & editing. **Ville E.J. Sirviö:** Investigation, Resources, Writing – review & editing. **FINEGO collaborative:** Data Curation, Writing - review & editing. **Joonas H. Kauppila:** Validation, Investigation, Resources, Data curation, Writing – review & editing. **Jesper Lagergren:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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