



## Original article

# Decreasing complication rates with stapled esophagojejunostomy following a learning curve

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### Abstract

**Background.** Recently, two reports of clinical trials on gastric cancer surgery have reported high mortality following extended lymph node dissection. In these reports, anastomotic leakage at the esophagojejunostomy was observed in approximately 10% of patients, with high mortality. These data highlight the importance of avoiding this complication. In this article, we report the use of a stapler to achieve a safe anastomosis, with low incidences of leakage and postoperative stenosis.

**Methods.** From January 1985 to December 1997, we performed 1234 esophagojejunal anastomoses at the National Cancer Center Hospital. Records of the 1234 patients were reviewed to evaluate changes in anastomotic techniques and changes in the incidence of anastomotic leakage. In this series, 588 stapled anastomoses were carried out between 1992 and 1997. These were evaluated to calculate the incidence of leakage and stenosis, with special reference to the use of supplementary sutures around the stapled anastomosis. Statistical analysis was performed by the  $\chi^2$  test.

**Results.** This series showed an overall increase in the use of staplers to form the esophagojejunal anastomosis, and a decrease in the incidence of leakage. In 1995, all anastomoses were stapled, with a leakage rate of less than 1.0%. In the last 6 years of the series (1992–1997), the leakage rate was 1.0% and the incidence of postoperative stenosis was 1.2%. The results were not improved by supplementary sutures around the stapled anastomosis.

**Conclusion.** These data show that a stapled esophagojejunal anastomosis without supplementary sutures is a safe way to create a esophagojejunal anastomosis, with results superior to those with hand suturing. We believe the stapled anastomosis should become the “gold standard” for esophagojejunal anastomosis.

**Key words** Learning curve · Esophagojejunostomy · Stapled anastomosis · Gastric cancer · Total gastrectomy

### Introduction

The results of the Dutch and the British randomized trials on the surgical treatment of gastric cancer demonstrated a high mortality after D2 (extended) nodal dissection, with the benefit of the D2 nodal dissection nullified by the high mortality [1–3]. In particular, the rates of esophagojejunal anastomotic leakage were 10% or more, with approximately 40% of these cases being lethal [1,2]. This highlights the importance of keeping early postoperative morbidity and mortality to a minimum by constructing a ‘safe’ anastomosis.

In the 1970s, circular stapling devices for the gastrointestinal tract were introduced in Japan [4]. Since then, the devices have been used more widely year by year to construct anastomoses. In the 1980s and early in the 1990s, many studies comparing stapled anastomosis and sutured anastomosis were reported [5–13], some of them being randomized control studies [5,6]. Some of these reports suggested that the rates of anastomotic leakage and stenosis were about the same for the stapled and the sutured anastomoses [5,6,8], while others suggested the leakage rate of the stapled anastomosis to be lower [7]. The only consistently reported disadvantage of the stapled anastomosis was the reduced cost benefit [5].

Since the early 1990s, there have been very few reports about stapled anastomotic techniques [14]. In this study, we re-evaluated the benefits of stapled and sutured anastomoses following the use of the stapler devices over the past decade. We report changes in the usage of the stapler devices and we document the complication rates associated with the use of stapler devices for esophagojejunal anastomosis in the 13 years 1985–1997.

## Patients and methods

The records of a series of 1234 consecutive patients who underwent gastrectomy and esophagojejunostomy at the National Cancer Center Hospital, from January 1985 to December 1997, were analyzed. There were 891 men and 343 women, ranging in age from 21 to 89 years (mean, 59.8 years). The anastomosis was made after total gastrectomy in 1144 patients and after proximal gastrectomy in 90 patients.

The methods used for esophagojejunal anastomosis were classified into three types, one-layered sutured, two-layered sutured, and stapled anastomosis. The anastomotic technique was selected by the staff surgeon, who was either the operator or the first assistant. The stapler devices (principally 25mm) used were the EEA (Auto Suture Japan, Tokyo, Japan) or ILS (Ethicon Endosurgery, Johnson & Johnson, Tokyo, Japan). All patients underwent radiographic study with water-soluble contrast medium on postoperative day 7 or 8. Our definition of anastomotic leakage included both clinical and nonclinical (radiographically detected) leakage. The clinical records of the 1234 patients were reviewed to deduce the incidence of anastomotic leakage with each of the anastomotic techniques. In order to evaluate the effect of supplementary sutures added after stapled anastomosis, we calculated the incidence of leakage and anastomotic stenosis in the 588 patients who underwent a stapled esophagojejunostomy between 1992 and 1997. Statistical analysis was performed by the  $\chi^2$  test, with  $P < 0.05$  considered significant.

## Results

Table 1 shows the leakage rates each year (1985–1997) according to the method of anastomosis. The use of the anastomotic stapler increased steadily during this period. In contrast, the leakage rate from stapled anastomoses decreased during the same period. After 1993, there was either none or one case of leakage during each year. There have been no deaths as a result of anastomotic leakage in these patients with stapled anastomoses. Prior to 1985, one-layered sutured anastomosis was the preferred method. The leakage rate from that type of anastomosis remained constant (although the use of this method declined), until 1991, when it ceased to be used at all. With the two-layered sutured anastomosis, the leakage rate decreased from 1985 to 1989, but increased again from 1990 to 1994. Since 1995, similarly, this method has not been used.

Changes in the usage rate of stapled anastomosis and in the incidence of leakage each year are shown in Fig. 1. The usage rate of the anastomotic stapler has in-

**Table 1.** Leakage of esophagojejunal anastomosis

Year	Stapler	One layer	Two layers	Total
1985	1/6 (16.7)	10/61 (16.4)	4/8 (50.0)	15/75 (20.0)
1986	4/39 (10.3)	10/39 (25.6)	1/8 (12.5)	15/86 (17.4)
1987	4/33 (12.1)	4/45 (8.9)	1/13 (7.7)	9/91 (9.9)
1988	3/53 (5.7)	4/30 (13.3)	0/6 (0.0)	7/89 (7.9)
1989	4/58 (6.9)	5/30 (16.7)	0/4 (0.0)	9/92 (9.8)
1990	1/76 (1.3)	1/10 (10.0)	3/9 (33.3)	5/95 (5.3)
1991	4/88 (4.5)	0/1 (0.0)	1/3 (33.3)	5/92 (5.4)
1992	3/84 (3.6)	0/2 (0.0)	3/6 (50.0)	6/92 (6.5)
1993	1/84 (1.2)	0/0 (0.0)	3/5 (60.0)	4/89 (4.5)
1994	0/88 (0.0)	0/0 (0.0)	1/2 (50.0)	1/90 (1.1)
1995	0/102 (0.0)	0/0 (0.0)	0/0 (0.0)	0/102 (0.0)
1996	1/105 (1.0)	0/0 (0.0)	0/0 (0.0)	1/105 (1.0)
1997	1/127 (0.8)	0/0 (0.0)	0/0 (0.0)	1/127 (0.8)

Figures in parentheses are percentages

One layer, One-layered manual anastomosis; two layers, two-layered manual anastomosis

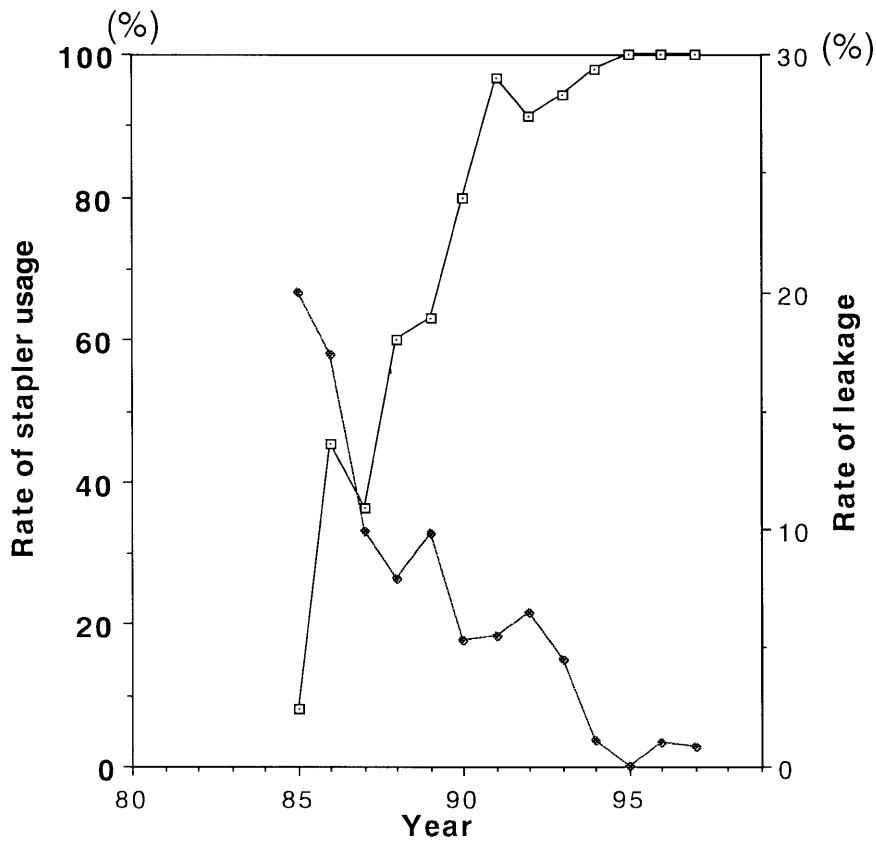
creased sharply since the introduction of this device, and, as a result, the rate of leakage has decreased. In 1995, a plateau was reached, in which the usage rate of the anastomotic stapler was 100% and the leakage rate had fallen to 0–1%.

Increases in stapler usage and the changes in incidence of leakage from stapled anastomosis are shown in Fig. 2. The rate of leakage from stapled anastomosis decreased sharply with increased experience in the use of the stapler.

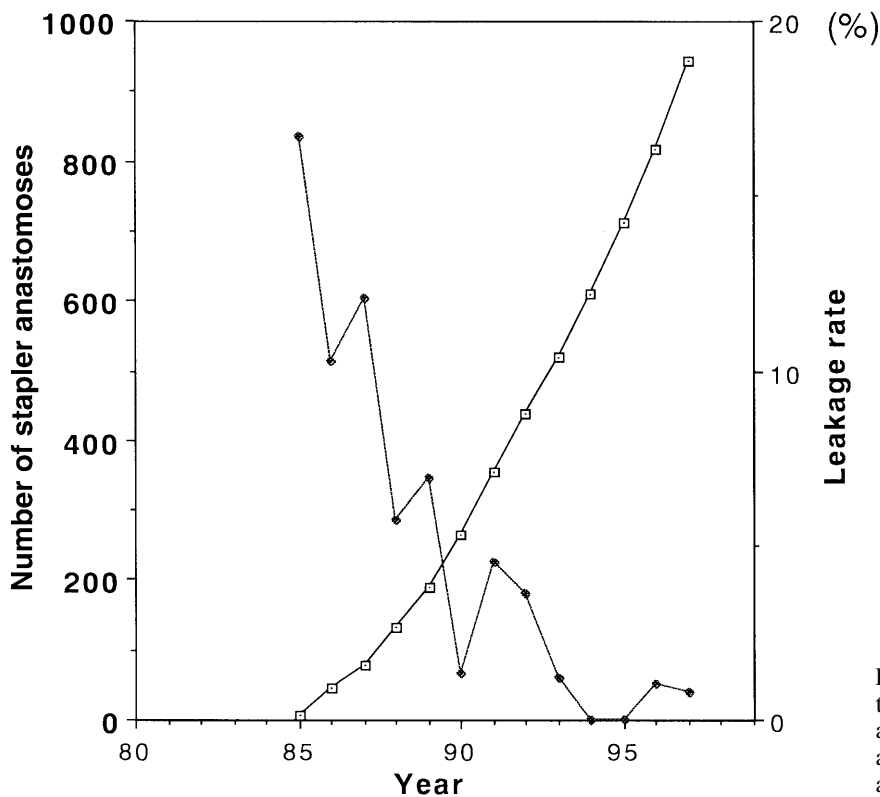
Table 2 shows the complication rates in patients who received the stapled anastomoses in recent years (1992–1997). A comparison of complication rates among these patients who had supplementary sutures (either partial or completely circumferential) in addition to staples and those without extra sutures is also shown in Table 2. There were no significant differences in complication rate between the groups.

## Discussion

Prior to 1990, the leakage rate for hand-sewn anastomoses had remained at 10%–25% for more than 20 years [15]. Therefore, anastomotic leakage used to be a most important post-operative complication. In 1985, stapler devices for esophagojejunal anastomoses were introduced at the National Cancer Center Hospital, and their use then grew steadily until 1995, when all the anastomoses were made with the stapler. In response to the increase in usage of the staplers, the rate of anastomotic leakage decreased accordingly. In the last 6 years of our series (1992–1997), the leakage rate after the stapled esophagojejunal anastomosis was 1.0%, and the postoperative stenotic rate was 1.2%. All these stenoses were membranous and easily dilated at endoscopy.



**Fig. 1.** Changes in rates of usage of stapler devices (*squares*) and leakage rates (*diamonds*) are shown. The usage rate increased rapidly, reaching more than 90% in 1991 and 100% in 1995. In response to this usage, the leakage rates decreased, reaching 1% or less in 1994



**Fig. 2.** Learning curves for stapler anastomosis are shown. The number of stapler anastomoses (*squares*) has been increasing and, as a result, the leakage rate of stapler anastomosis (*diamonds*) has decreased

**Table 2.** Comparison of complication rates of stapler anastomosis with and without supplementary sutures in recent years (1992–1997)

	Stapler only	Partially supplemented	Circumferential supplemented	Total
Leakage	0/108 (0.0)	3/332 (0.9)	3/148 (2.0)	6/588 (1.0)
Stenosis	2/108 (1.9)	4/332 (1.2)	1/148 (0.7)	7/588 (1.2)

Figures in parentheses are percentages

There were no significant differences in rates among stapler only, partially supplemented sutured, and circumferential supplemented sutured

These results with staplers, with consistently low complication rates compared with those for conventional sutures, even in the skilled hands of an upper-gastrointestinal specialist, suggest that the stapled anastomosis should become the ‘gold standard’ [14].

A reported disadvantage of the stapled anastomosis is the high cost of the stapler devices [5]. However, the cost of increased medical care in a patient with a leaking anastomosis, is on average, equal to roughly, the cost of 20–25 staplers. In this case, with a leakage rate of 5% or more in patients with a sutured anastomosis, the cost benefit is in favor of the use of a stapler, with the decrease in the leakage rate to 1%.

In the early era of the stapled anastomosis, it was the usual practice to add supplementary sutures around the stapled anastomosis, because of the lack of confidence in the capacity of the staples. Our data, however, show the leakage rate of stapled anastomoses without supplementary sutures to be 0.0%. Therefore, supplementary sutures are not needed after “successful” stapled anastomosis.

Many studies comparing stapler and manual anastomoses for esophagojejunostomy were reported in the 1980s [5–10]. Most of them reported equivalent leakage rates [5,6,8,10], and a few reported lower leakage rates with the stapled anastomosis, but the difference was not so striking [4]. The reported leakage rates of stapled anastomoses were 2.3%–14.3% [4–13,16–18], whereas our leakage rate of stapled anastomoses was 5.9% in the earlier era (1985–1991). In this report, we clearly demonstrate a learning curve, with vastly improved results for the technique in recent years. Our leakage rate of stapled anastomosis in the recent years of the study (1992–1997) was 1.0%. We performed sutured anastomoses for more than 20 years before the induction of the stapler devices. Many studies have compared stapled and sutured anastomoses in the early era of the staplers [5–10], with unfamiliar stapler techniques and accustomed conventional sutured anastomosis being compared. This is a common problem in any study related to surgical technique. The techniques should be evaluated in the light of the learning curve and when sufficient time has elapsed for the technique to have

become more established. The recently reported results of the two randomized clinical trials on the effect of lymph node dissections for gastric cancer (noted in the “Introduction”) may suffer from this bias as well [1,2].

In conclusion, it is proposed that the stapler anastomosis is now the ‘gold’ standard method for esophagojejunostomy. It can be performed safely when it is done by an experienced surgical team.

**Acknowledgments** The authors express their thanks to Dr. Peter David for his checking of the English. Our thanks also go to Ms. Naomi Sugimoto for her gathering of the patients’ records.

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