

**“SHORT TERM AND LONG TERM OUTCOMES OF
STAPLED VERSUS HANDSEWN
OESOPHAGOJEJUNAL ANASTOMOSIS AFTER
TOTAL GASTRECTOMY”**

Dissertation submitted to
THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY
in partial fulfilment of the requirements for the
Award of the degree of
M.Ch BRANCH – VI

**SURGICAL GASTROENTEROLOGY AND
PROCTOLOGY**



**THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY
CHENNAI**

AUGUST 2013

CERTIFICATE

This is to certify that the dissertation titled “**Short term and Long term outcomes of Stapled versus Hand Sewn Oesophagojejunal Anastomosis after Total gastrectomy**” submitted by **DR.C.Kolandasamy** appearing for **M.Ch. (SurgicalGastroenterology and Proctology)** degree examination in August 2013 is a bonafide record, of work done by him under my guidance and supervision in partial fulfilment of requirement of the Tamil Nadu Dr.M.G.R.Medical University, Chennai. I forward this to the Tamil Nadu Dr.M.G.R.Medical University, Chennai.

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DECLARATION

I solemnly declare that this dissertation titled “**Short term and Long term outcomes of Stapled versus Hand Sewn Oesophagojejunal Anastomosis after Total Gastrectomy**” was prepared by me in the Department of Surgical Gastroenterology and Proctology, Centre of Excellence for Upper Gastrointestinal Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai under the guidance and supervision of **Prof.S.M.Chandramohan**, MCh, FACS, Professor & Head of the Department of Surgical Gastroenterology and Proctology, Centre of Excellence for Upper Gastrointestinal Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai. This dissertation is submitted to The Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfilment of the university requirements for the award of the degree of M.Ch Surgical Gastroenterology and Proctology.

Place: Chennai

Date:

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INDEX

Sl.NO	CONTENTS	PAGE
1	Introduction	1
2	Rationale for the Study	3
3	Aim of the Study	4
4	Review of Literature	5
5	Materials and Methods	6
6	Definitions	16
7	Statistical Analysis	18
8	Results	19
9	Discussion	57
10	Conclusion	62
11	Bibliography	63
12	Appendix	
	Case Record Form	
	Consent Forms	
	Master Chart	
	Ethical Committee approval	

INTRODUCTION

Surgery remains the mainstay of treatment for OG Junction carcinoma and proximal body gastric carcinoma, with chemotherapy and chemoradiotherapy as adjuvant or neoadjuvant treatment¹.

The majority of gastric cancers are still diagnosed at an advanced stage. Total gastrectomy followed by D2 dissection offers the best prospects in term of overall survival². After the surgery, complications in terms of post operative morbidity and mortality are related to the oesophagojejunal anastomosis.

Oesophagojejunal anastomosis is the Achilles heel of total gastrectomy. Since the introduction of the first mechanical stapling devices³, a debate started about whether mechanical staplers or manual sutures produce better results. This debate continued well into the nineties, when very large studies settled the debate in favor of stapled anastomosis⁴.

Oesophagojejunostomy, using a circular stapler or hand sewn sutures, is a standard technique for Roux-en-Y reconstruction after total gastrectomy. Recently, mechanical anastomosis has been considered to be a safe way to create an oesophagojejunostomy, with leakage rates equivalent⁵⁻⁷ or even superior^{4, 8} to those of hand-sewn anastomosis.

Improvements in suturing techniques allowed improvement in the results of handsewn anastomosis, thereby previously described failure rates of about 15 percent no longer appropriate.

RATIONALE FOR THE STUDY

Trials comparing different anastomotic techniques have arrived at different conclusions. This study is to compare the short term and long term outcomes of stapled versus hand sewn esophagojejunal anastomoses after total gastrectomy for OG Junction carcinoma and proximal gastric carcinoma in our super specialty department, hence formulate a standard method of patient selection, type of anastomosis and perioperative care to achieve good outcome after total gastrectomy.

AIM OF THE STUDY

To compare the short term and long term outcomes between stapled versus hand sewn oesophagojejunal anastomosis after total gastrectomy for OG junction carcinoma and proximal gastric carcinoma.

To analyze the perioperative variables like duration of surgery, margins, postoperative day of initiating oral intake, incidence of anastomotic leakage, incidence of stricture, morbidity, mortality and hospital stay between the groups of patients undergoing mechanically stapled and hand sewn oesophago-jejunal anastomosis and improve the perioperative care to achieve good outcomes after total gastrectomy.

REVIEW OF LITERATURE

Retrospective study by Ikeda Y et al, handsewn single layer suturing was considered to be safe anastomoses and is thought to be reducing anastomotic failure for oesophagojejunostomy.⁷

Randomized controlled trials showed that duration of surgery, incidence of anastomotic leakage, stricture, morbidity and hospital stay did not differ significantly between the groups of patients undergoing handsewn and stapled oesophagojejunal anastomosis.^{5, 6} It indicates that handsewn and mechanically stapled esophagojejunostomy anastomoses allow the same high standard of performance.

Article by Takeyoshi et al, patients who underwent esophagojejunal anastomosis either by stapled or handsewn, following a total gastrectomy for gastric carcinoma were reviewed. While there was no difference in the anastomotic stricture rate, the incidence of anastomotic leak was significantly lower in the stapled group.

Over the years stapler anastomosis have become popular leading to several studies publishing technical refinements for performing Oesophagojejunostomy.⁹ Hence, the mechanical stapler facilitated the construction of a reliable and rapid oesophagojejunal anastomosis.

MATERIALS AND METHODS

Patients attending OPD in Department of Surgical Gastroenterology, Centre of Excellence for Upper Gastrointestinal Surgery, Rajiv Gandhi Government General hospital between August 2010 to February 2013 with upper gastrointestinal symptoms and signs were examined and evaluated by imaging studies, upper GI endoscopy and biopsy and details of those patients who found to have adenocarcinoma of OG junction & proximal gastric adenocarcinoma were segregated in data base.

All the data for analysis were collected retrospectively and the clinical parameters were noted in a proforma. Besides age and gender, the chief complaints, co-morbid illness, nature of diet intake, habit of smoking and alcohol consumption were also noted. Findings on physical examination such as pallor, pedal edema and jaundice were noted. Clinical findings of the abdomen like upper abdominal mass, hepatomegaly and free fluid and per rectal examination findings like rectal deposits were noted.

CBC, RFT, LFT and viral markers status were noted. Ultrasonogram of abdomen, upper GI endoscopy, biopsy report and contrast enhanced computerized tomography findings were noted for all patients.

This is a retrospective study.

The two arms in our studies were

- Stapled oesophagojejunal anastomosis arm
- Hand sewn oesophagojejunal anastomosis arm

Patients undergoing total gastrectomy for adenocarcinoma of OG junction & proximal gastric adenocarcinoma were selected for our study. The sample size is 63 patients. Hand sewn anastomoses was done by single layer, interrupted sutures using 3-0 vicryl in 15 patients and stapler anastomoses was done by using SDH 25mm circular stapler in 48 cases.

We excluded the patients who had total gastrectomy for stump carcinoma, recurrent carcinoma stomach and palliative resections, proximal gastrectomy for proximal gastric adenocarcinoma / GIST, transhiatal oesophagectomy for Carcinoma OG Junction extending to distal oesophagus and multi organ resection.

Preoperatively an informed consent was obtained from all the patients explaining the nature of illness, the magnitude of surgery, morbidity and mortality.

All the patients had adequate preoperative preparation before surgery. After opening the abdomen, assessment for resectability of the tumour was done and surgery is proceeded.

Total gastrectomy is done by dividing first part of duodenum using TLC 55mm and dividing esophagus about 5cm from proximal to tumor margin after complete mobilization of the stomach. Roux limb is prepared by dividing the Jejunum about 20- 30 cm from DJ flexure brought retrocolically and oesophagojejunal anastomosis done by stapled or handsewn anastomoses.

Purse string suture had taken with 2-0 prolene in distal oesophagus, anvil passed into distal oesophagus and purse string suture tied around the anvil head tightly, leaving no slack. The stapler gun was inserted through the free jejunal loop and an end-to-side stapled esophagojejunal anastomosis was made by SDH 25 stapler. Doughnuts were examined to assess the integrity of the anastomosis. The jejunal stump was closed with TRH 30 or TLC 55 stapler or handsewn sutures.

Hand sewn oesophagojejunal anastomosis was done by single layer interrupted sutures in an end to side fashion with 3.0 vicryl suture.

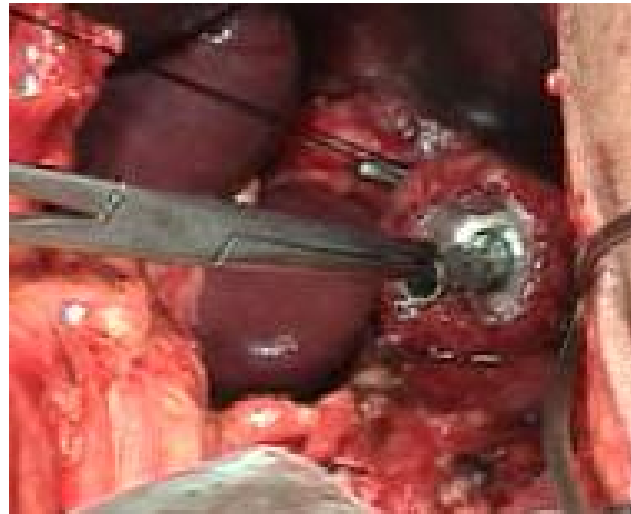
Other technical details were identical in both groups.

STAPLED OESOPHAGOJEJUNAL ANASTOMOSIS

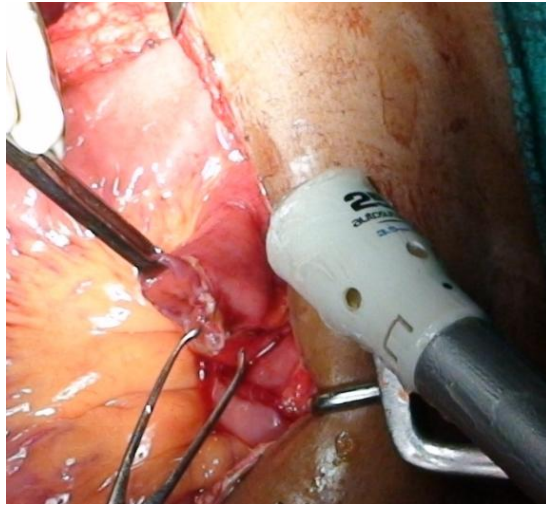
CUT END OF LOWER OESOPHAGUS



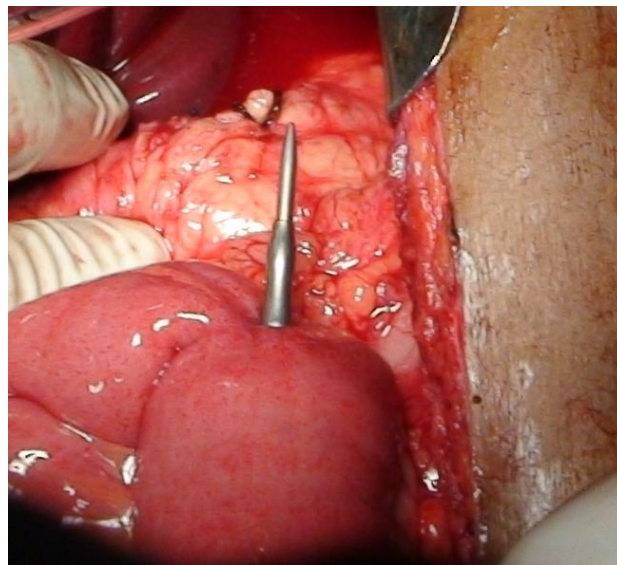
INTRODUCTION OF ANVIL



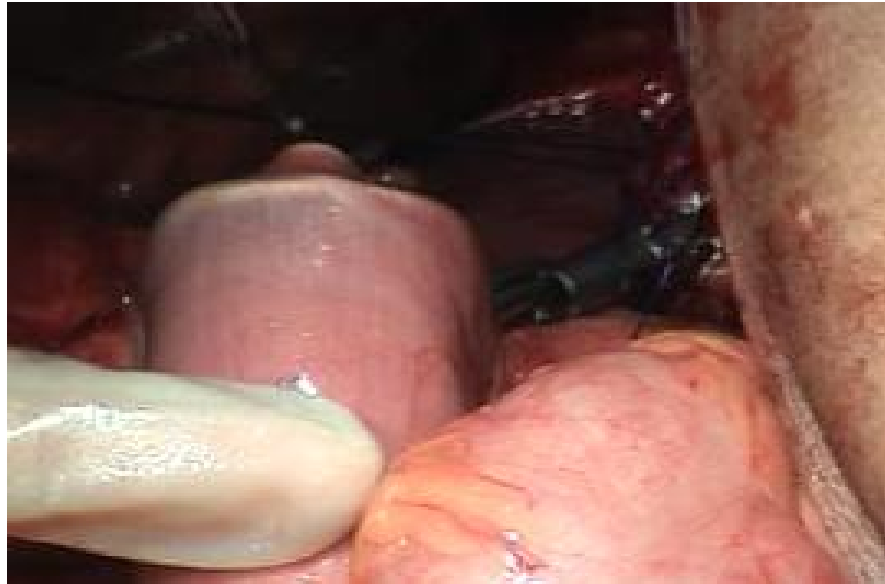
INTRODUCTION OF STAPLER GUN INTO JEJUNAM



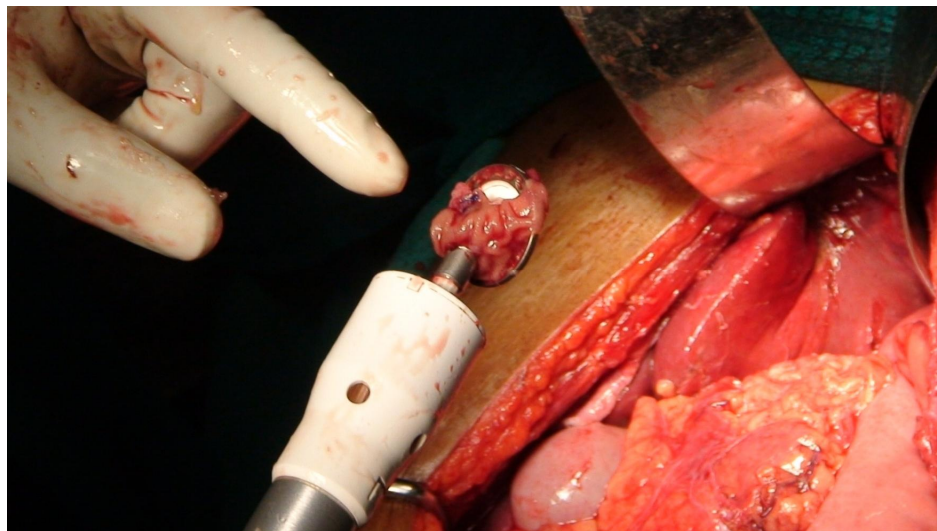
PROXIMAL STAPLER GUN SPIKE



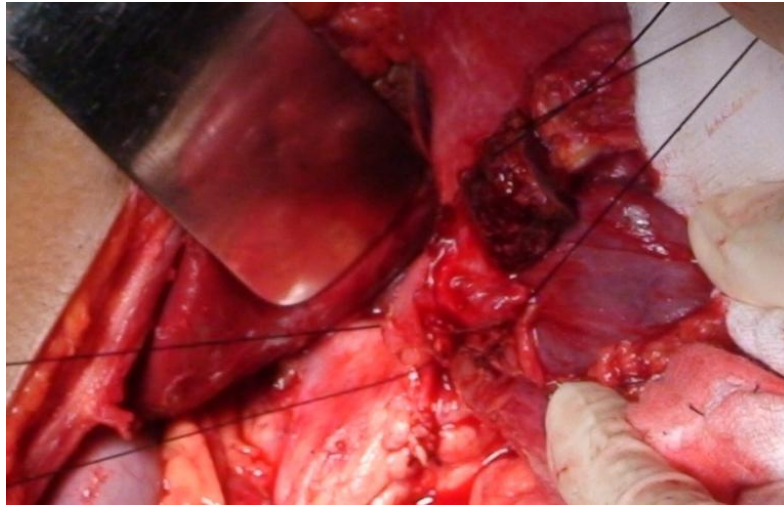
MATING OF PROXIMAL GUN SPIKE WITH ANVIL



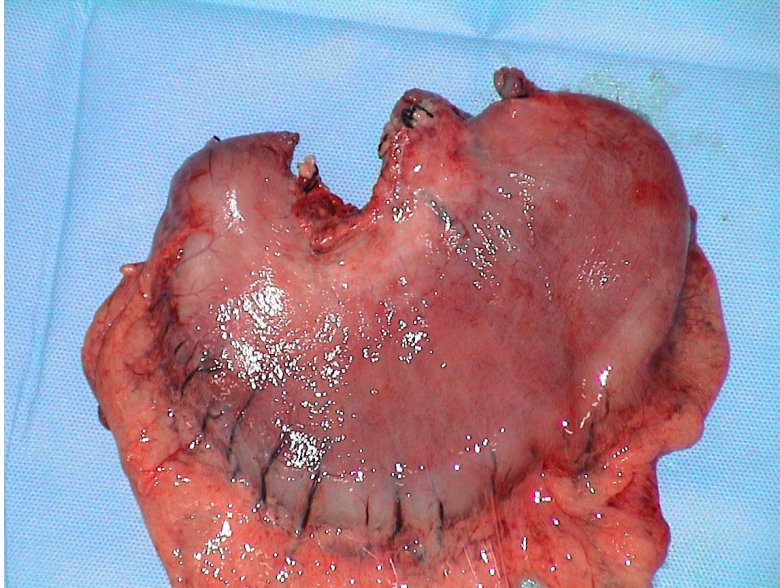
DOUGHNUT



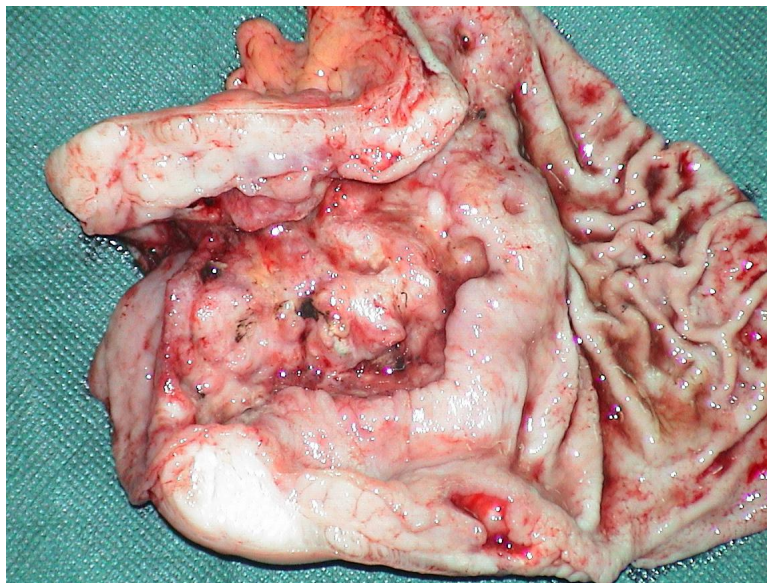
HANDSEWN OESOPHAGOJEJUNAL ANASTOMOSIS



GROSS SPECIMEN



CUT SPECIMEN



In both the groups, after completing the anastomosis intraoperative leak test was performed by distending the anastomosis with air through Ryle's tube to check the integrity of the anastomosis.

Proximal end of the jejunum was anastomosed in side to side or end to side fashion with the jejunum 40cm from the oesophagojejunal anastomotic site by hand sewn anastomosis. FJ done by modified Witzel's technique in all patients. Pad and instruments count verified before closure. Abdomen closed after complete hemostasis with bilateral flank tube drain, positioned close to the duodenal stump and gastrojejunal anastomosis respectively.

Post operatively in doubtful cases of anastomotic leak before starting oral liquids, anastomotic integrity was checked by contrast study using water-soluble contrast medium (gastrograffin or iohexal).

After surgery variables like operating time, blood loss, incidence of anastomotic leakage, incidence of stricture, margin, postoperative day of initiating oral intake, hospital stay, morbidity and 30 day mortality or mortality up to the time of discharge if this was longer were documented and analyzed.

If clinical suspicion of anastomotic leakage was present initial bedside USG abdomen followed by CT Abdomen plain and contrast (i.v and oral) was done.

The study protocol was approved by the Ethical committee of the Tamil Nadu Dr MGR Medical University, Chennai.

DEFINITIONS

The complications after total gastrectomy as noted in the proforma were defined as follows:

Anastomotic leak

Radiologically or clinically detectable collection after 5th postoperative days with pain, pyrexia considered as leak.

Anastomotic stricture

Recurrence of dysphagia due to endoscopically or radiologically detected narrowing defined as stricture.

Intra-abdominal collection

Any collection detected by ultrasonogram or CECT of more than 5 cm is defined as intra abdominal collection.

Wound infection

Any collection of pus or fluid at the operated site with mild fever, leucocytosis and local inflammatory signs in the absence of any major complications is defined as wound infection.

Pneumonitis

Any post-operative lung signs with fever and diminished air entry is defined as basal pneumonitis and aggressively treated by ambulation, chest physiotherapy, antibiotics and nasal oxygen.

Mortality

30 day mortality or mortality up to the time of discharge if this was longer was taken for statistical analysis.

STATISTICAL ANALYSIS

The data collected in the proforma were entered in an excel sheet of Microsoft office software and inference obtained after statistical analysis. The mean and standard deviation were reported for continuous variables and for categorical variables proportions were computed. For discrete data proportion are computed and the mean and standard deviation are computed for the continuous data. The chi square test was applied to compare the proportions between the groups. The independent t-test was used to compare the means between the groups. All analyses were two tailed and $p < 0.05$ was considered significant. SPSS version 16.0 was used for data analysis.

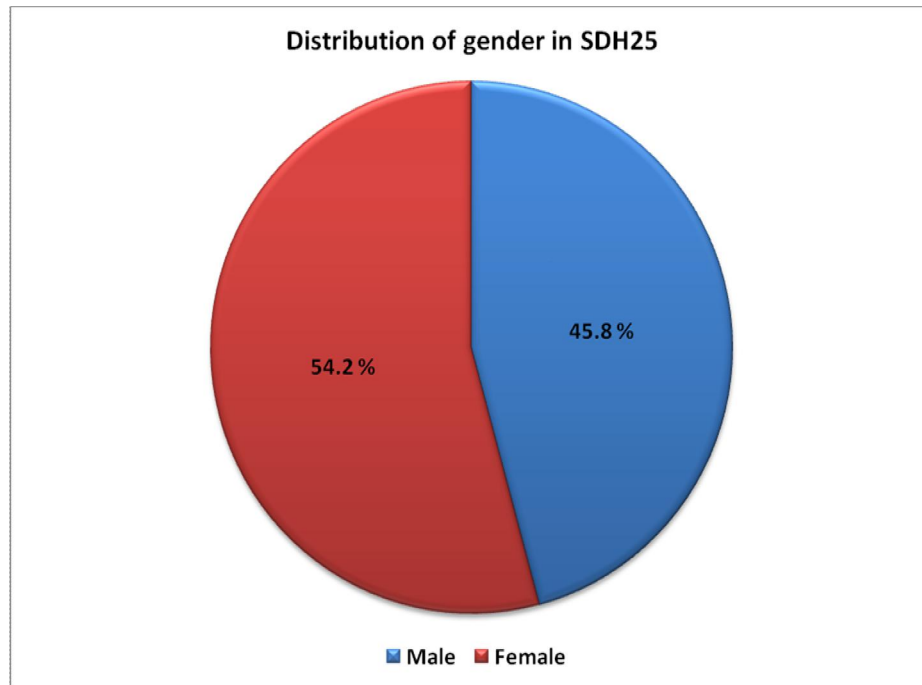
RESULTS

This retrospective analysis was done in 63 patients who had undergone total gastrectomy for proximal gastric carcinoma and OGJ carcinoma.

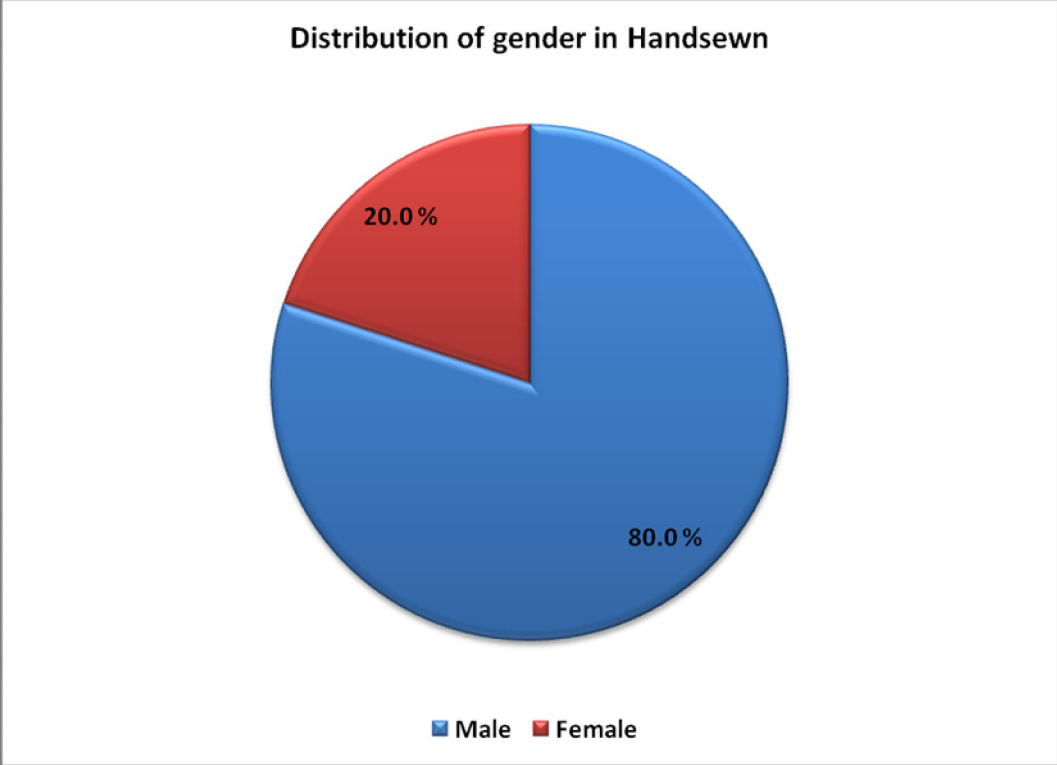
Among the total 63 patients 34 patients (54%) were males and 29 patients (46%) were females, minimum age was 26 years and maximum age was 70 years.

Table .1 Sex Distribution

		Sex		Total
		Male	Female	
SDH25	Count	22	26	48
	% within group	45.8%	54.2%	100.0%
Hand sewn	Count	12	3	15
	% within group	80.0%	20.0%	100.0%
Total	Count	34	29	63
	% within group	54.0%	46.0%	100.0%



Among the stapler group 48 patients, 22 patients (45.8%) were males and 28 patients (54.2%) were females, minimum age was 27 years and maximum age was 65 years.



Among the handsewn group 15 patients, 12 patients (80%) were males and 3 patients (20%) were females, minimum age was 26 years and maximum age was 70 years.

Table.2 Age distribution

Group	N	Mean	Std. Deviation	P-value
Age SDH25	48	51.06	9.990	0.483
Handsewn	15	53.33	13.441	

The mean age for stapler group patient was 51.1years with a standard deviation of 9.99 and p value=0.483, the mean age for hand sewn group patient was 53.3 years with a standard deviation of 13.44 and pvalue=0.483

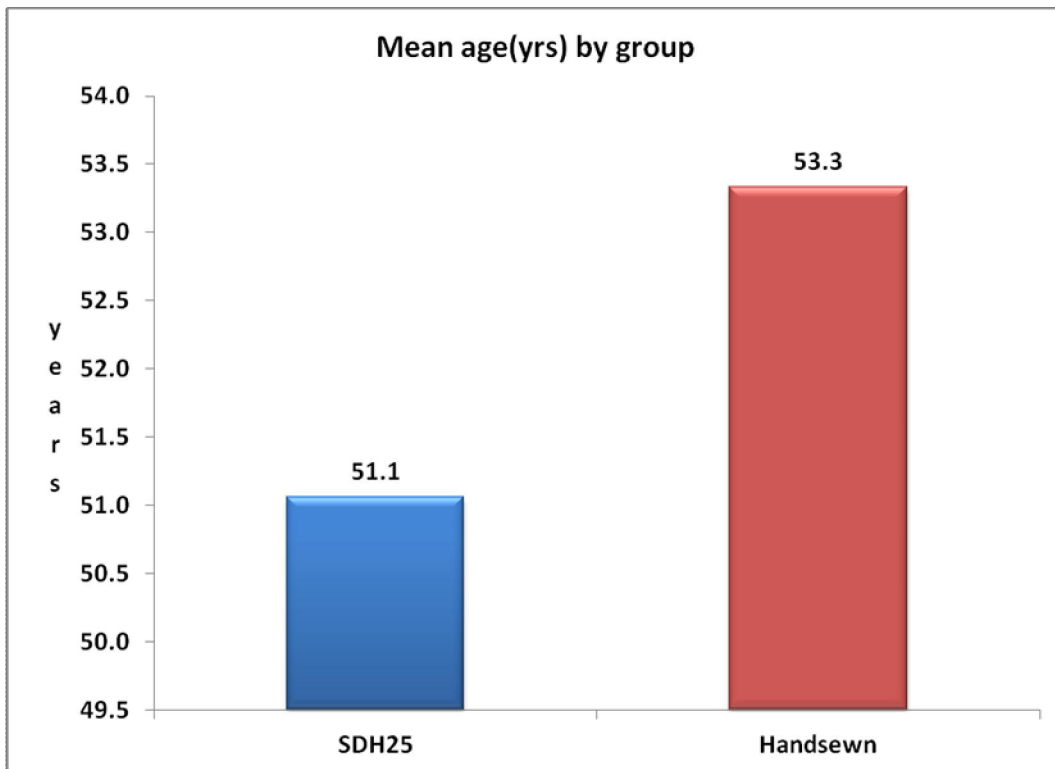
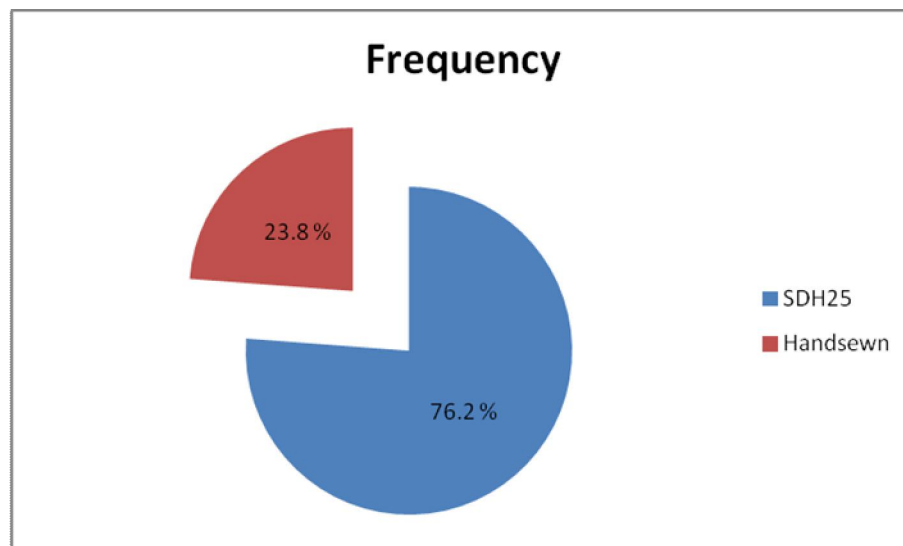


Table.3 Types of Anastomosis

	Frequency	Percentage
SDH25	48	76.2
Handsewn	15	23.8
Total	63	100.0

Among 63 patients, 48 patients (76.2%) had stapled oesophagojejunal anastomosis and 15(23.8 %) had hand sewn oesophagojejunal anastomosis.



CLINICAL PRESENTATION:

87% of total group patients, 93.8% of stapler group patients and 66.7% of handsewn group patients had dysphagia at presentation.

Table. 4 Symptoms – Dysphagia

		Dysphagia		Total
		Yes	No	
SDH25	Count	45	3	48
	% within group	93.8%	6.2%	100.0%
Handsewn	Count	10	5	15
	% within group	66.7%	33.3%	100.0%
Total	Count	55	8	63
	% within group	87.3%	12.7%	100.0%

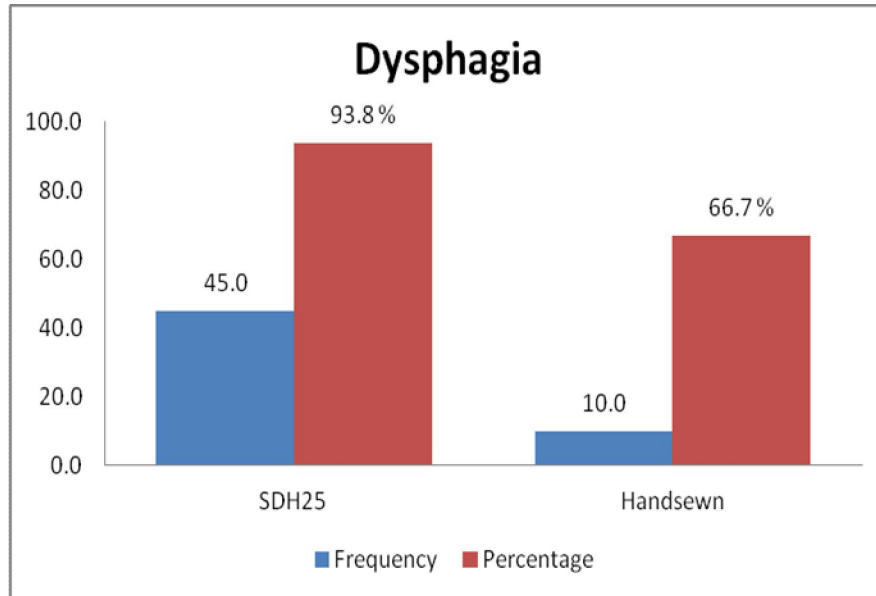


Table. 5 Symptoms – Vomiting

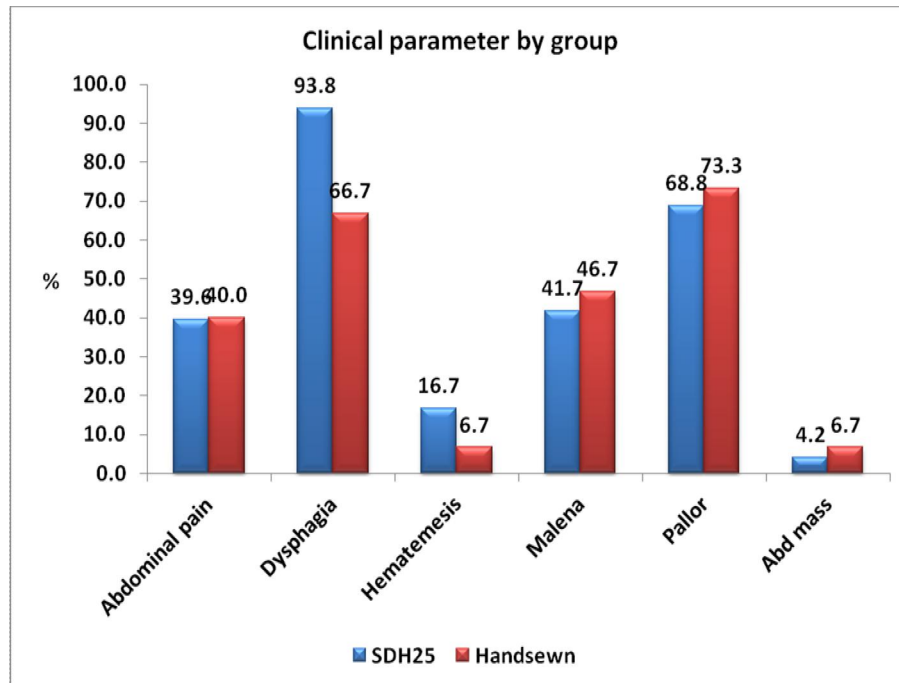
		Vomiting		Total
		Yes	No	
SDH25	Count	13	35	48
	% within group	27.1%	72.9%	100.0%
Handsewn	Count	2	13	15
	% within group	13.3%	86.7%	100.0%
Total	Count	15	48	63
	% within group	23.8%	76.2%	100.0%

23.8% of total group patients, 27.1% of stapler group patients and 13.3% of handsewn group patients had vomiting at presentation.

Table. 6 Symptoms – Abdominal pain

		Abd. Pain		Total
		Yes	No	
SDH25	Count	19	29	48
	% within group	39.6%	60.4%	100.0%
Handsewn	Count	6	9	15
	% within group	40.0%	60.0%	100.0%
Total	Count	25	38	63
	% within group	39.7%	60.3%	100.0%

39.6% of stapler group patients and 40% of handsewn group patients had abdominal pain at presentation.



16.7% of stapler group patients and 6.7% of handsewn group patients had hematemesis, 41.7% of stapler group patients and 46% of handsewn group patients had malena and 68.8% of stapler group patients and 73.3% of handsewn group patients had pallor at presentation.

Table.7 Signs – Abdominal Mass

		Abd. Mass		Total
		Yes	No	
SDH25	Count	2	46	48
	% within group	4.2%	95.8%	100.0%
Handsewn	Count	1	14	15
	% within group	6.7%	93.3%	100.0%
Total	Count	3	60	63
	% within group	4.8%	95.2%	100.0%

Only 4.2% of stapler group patients and 6.7% of handsewn group patients had abdominal mass at presentation, rest of the patients not had abdominal mass at presentation.

Table. 8 Symptoms - Loss of Appetite & Weight

		Loss of Appetite & Weight		Total
		Yes	No	
SDH25	Count	46	2	48
	% within group	95.8%	4.2%	100.0%
Handsewn	Count	13	2	15
	% within group	86.7%	13.3%	100.0%
Total	Count	59	4	63
	% within group	93.7%	6.3%	100.0%

93.7% of total group patients, 95.8% of stapler group patients and 86.7% of handsewn group patients had loss of appetite and loss of weight at presentation.

Table. 9 Co morbidity - Diabetes Mellitus

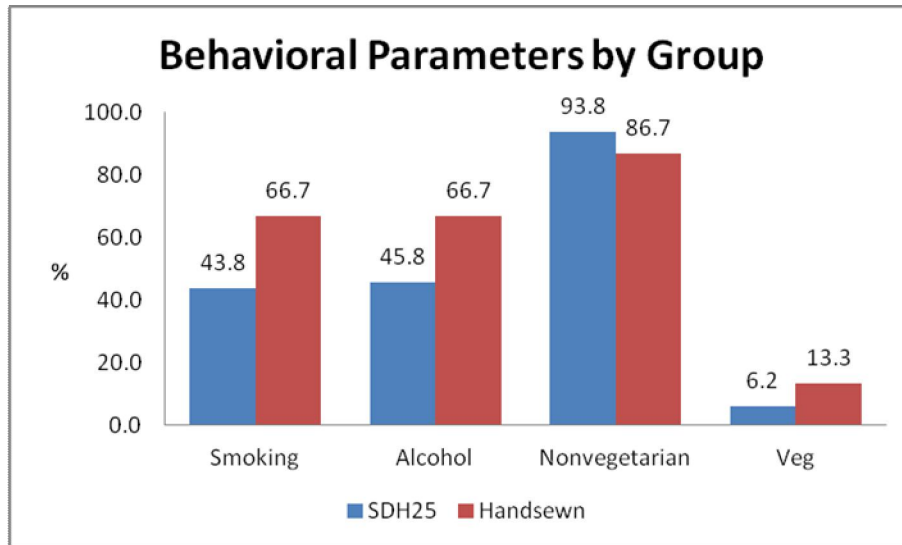
		DM		Total
		Yes	No	
SDH25	Count	3	45	48
	% within group	6.2%	93.8%	100.0%
Handsewn	Count	0	15	15
	% within group	0%	100.0%	100.0%
Total	Count	3	60	63
	% within group	4.8%	95.2%	100.0%

On evaluating the patients for co-morbid illness only 5% of patients had diabetes mellitus and majority of the patients were non diabetics.

Table. 10 Co morbidity – Systemic Hypertension

		SHT		Total
		Yes	No	
SDH25	Count	2	46	48
	% within group	4.2%	95.8%	100.0%
Handsewn	Count	0	15	15
	% within group	.0%	100.0%	100.0%
Total	Count	2	61	63
	% within group	3.2%	96.8%	100.0%

Only 3.2 % of patients had systemic hypertension and majority of the patients were not hypertensive.



Regarding the personal habits 43.8% of stapler group patients and 66.7% of handsewn group patients were smokers, 45.8% of stapler group patients and 66.7% of handsewn group patients were alcoholics.

Regarding the dietary habits 93.8% of stapler group patients and 86.7% of handsewn group patients were non-vegetarians, 6.2% of stapler group patients and 13.3% of handsewn group patients were vegetarians.

Table.11 Signs – Pallor

		Pallor		Total
		Yes	No	
SDH25	Count	33	15	48
	% within group	68.8%	31.2%	100.0%
Handsewn	Count	11	4	15
	% within group	73.3%	26.7%	100.0%
Total	Count	44	19	63
	% within group	69.8%	30.2%	100.0%

On clinical examination

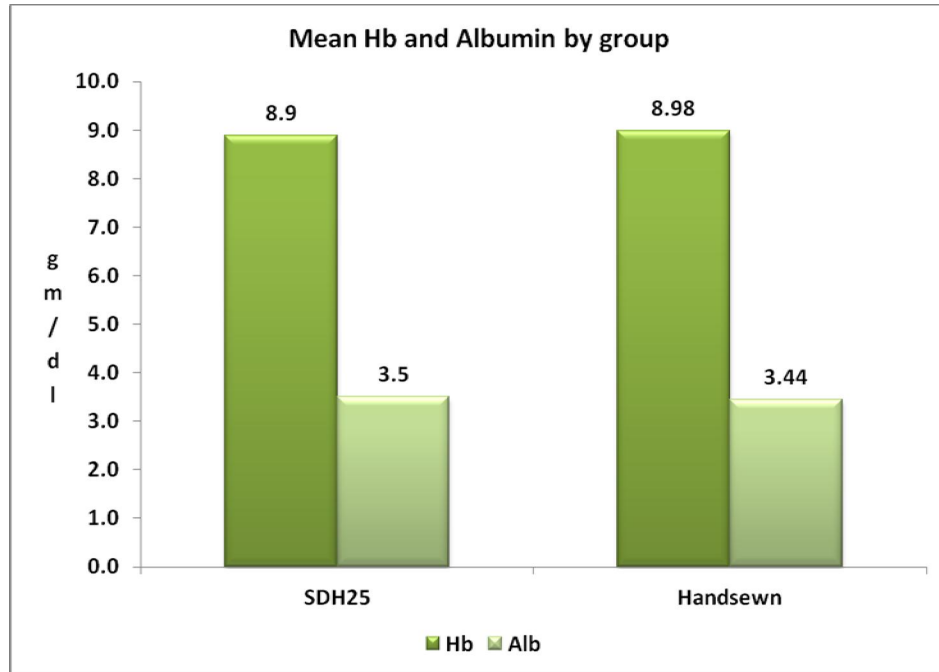
Majority of the patients, 68.8% of stapler group and 73.3% of handsewn group had pallor at presentation.

Biochemical Parameters

In our study the mean hemoglobin concentration was 8.9 gm% with lowest value of 4.9 gm% and highest value of 14.0 gm% and the need for preoperative transfusion was decided when hemoglobin was less than 8gm% which was not statistically significant with p value 0.901.

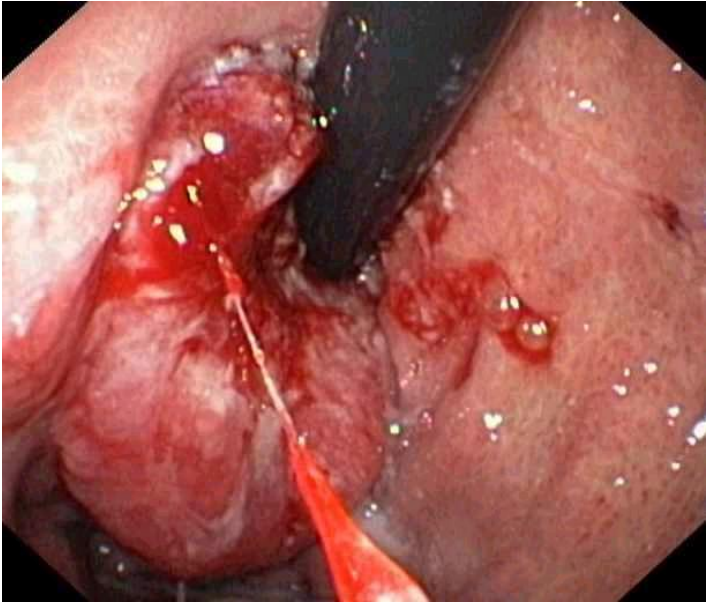
Table.12 Biochemical Parameters – Hemoglobin and Albumin

Group		N	Mean	Std. Deviation	P-value
Hb	SDH25	48	8.892	2.2975	0.901
	Handsewn	15	8.980	2.6892	
Alb	SDH25	48	3.506	.5025	0.660
	Handsewn	15	3.440	.5207	



The mean serum albumin was 3.5g with lowest at 2.5 g and highest at 4.2 g% was not statistically significant with p value 0.660.

OGD and biopsy and Multi CECT or CECT was done in all patients to assess the extent, respectability and to confirm diagnosis.



The patients in the study group were staged by AJCC 7th edition (2010) TNM staging classification.

The stage distribution of our patients is as follows:

Table.13 Stage Distribution

		STAGE		Total
		Stage II	Stage III	
SDH25	Count	8	40	48
	% within group	16.7%	83.3%	100.0%
Hand sewn	Count	4	11	15
	% within group	26.7%	73.3%	100.0%
Total	Count	12	51	63
	% within group	19.0%	81.0%	100.0%

From the above data, the commonest stage for which total gastrectomy was done in our institution was stage III (81%), followed by stage II (19%). Which was not statistically significant with p value = 0.457.

This clearly shows that we most commonly come across advanced gastric cancer patients.

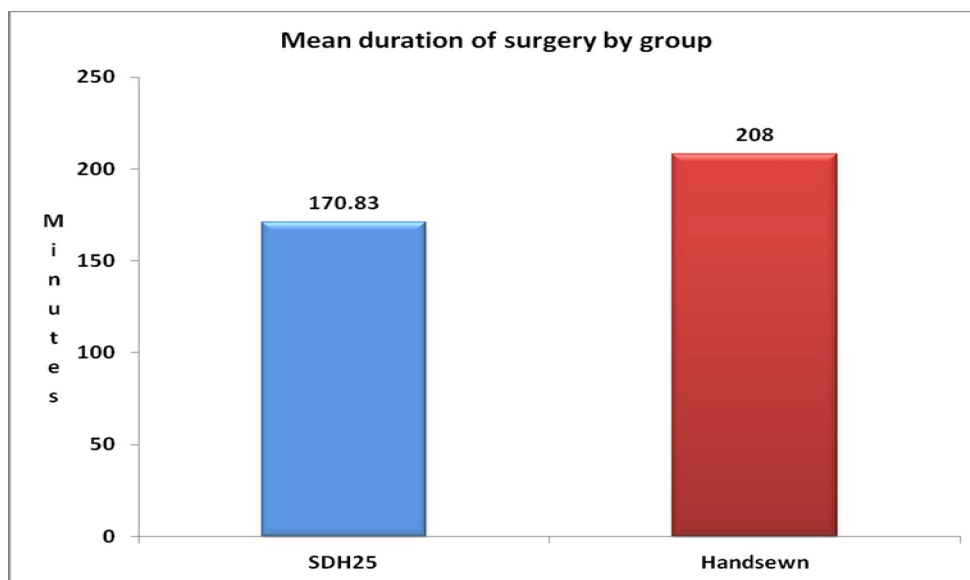
Diagnostic laparoscopy was done in all cases to detect peritoneal and surface liver metastasis and then proceeded to total gastrectomy.

Duration of Surgery

The mean duration of surgery was 170.83 mins for stapled esophagojejunal anastomoses with shortest duration of 140 mins, longest duration of 200 mins and standard deviation of 14.85. The mean duration of surgery was 208 mins for hand sewn esophagojejunal anastomoses with shortest duration of 190 mins, longest duration of 220 mins and standard deviation of 8.61 and it was statistically significant with p value = 0.000

Table.14 Duration of Surgery

Group	N	Mean	Std. Deviation	P-value
Duration SDH25	48	170.83	14.852	0.000
Handsewn	15	208.00	8.619	

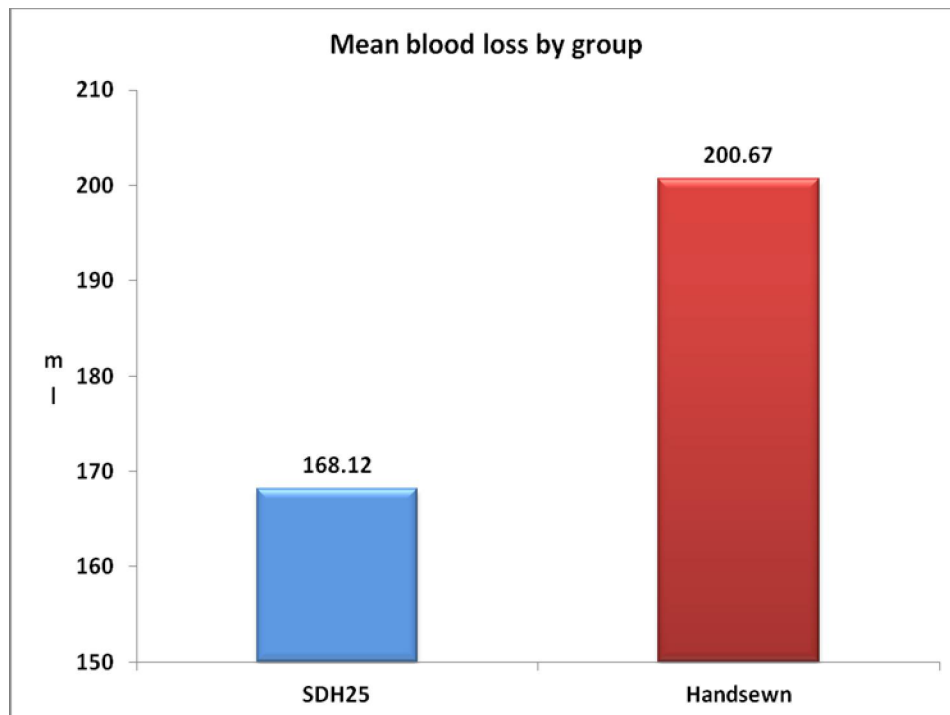


Blood Loss

The mean blood loss was 168 ml for stapled esophagojejunal anastomoses with standard deviation of 38.24 and 201 ml for hand sewn esophagojejunal anastomoses with standard deviation of 29.14. Blood loss was statistically significant with p value = 0.002.

Table.15 Blood Loss

	Group	N	Mean	Std. Deviation	P-value
Blood Loss	SDH25	48	168.12	38.241	0.002
	Handsewn	15	200.67	29.147	



Blood transfusion

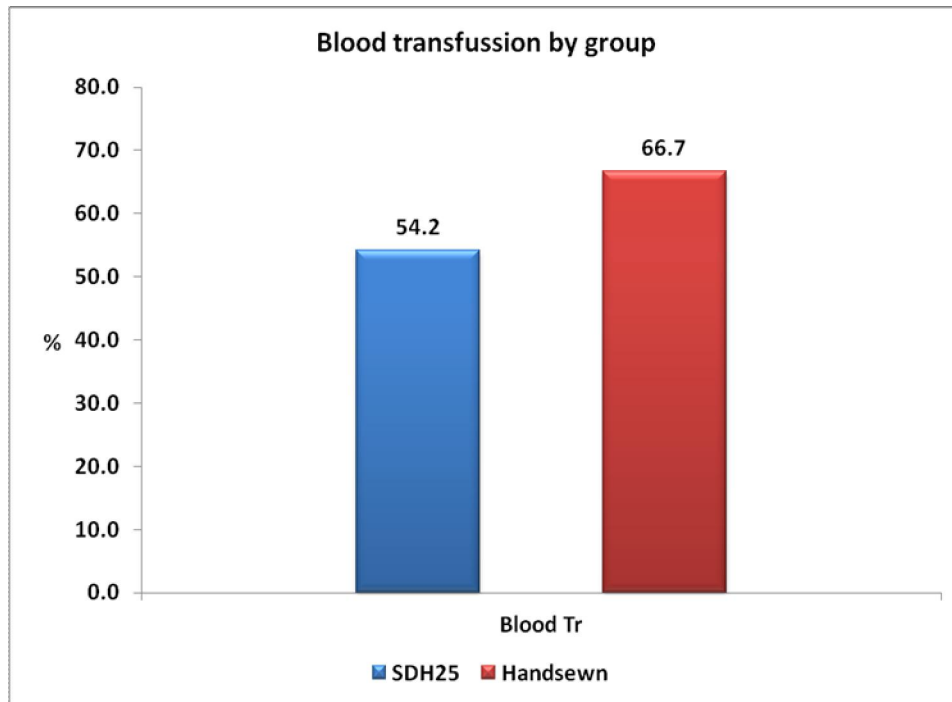
The need for preoperative transfusion was decided when hemoglobin was less than 8gm%.

Blood transfusion was done in 54.2% of stapled esophagojejunal anastomoses patients and 66.7% of hand sewn esophagojejunal anastomoses patients. Which was not statistically significant with p value = 0.552.

Table.16 Blood Transfusion Rate

		Blood Transfusion		Total
		Yes	No	
SDH25	Count	26	22	48
	% within group	54.2%	45.8%	100.0%
Handsewn	Count	10	5	15
	% within group	66.7%	33.3%	100.0%
Total	Count	36	27	63
	% within group	57.1%	42.9%	100.0%

There was slightly more blood loss in hand esophagojejunal anastomoses group than stapled esophagojejunal anastomoses group. But blood transfusion was not statistically significant with p value=0.552.



ANASTOMOTIC LEAK

Among 63 patients, 48 patients (76.2%) had stapled esophagojejunal anastomosis and 15(23.8 %) had hand sewn oesophagojejunal anastomosis.

Oesophagojejunal anastomotic leak in stapler anastomosis group was present in 1 patient (2.1%) and in hand sewn anastomosis group were present in 2 patients (13.3%).They were not statistically significant with p value of 0.138.

Table.17 Complications - Anastomotic Leak

		Anastomotic Leak		Total
		Yes	No	
SDH25	Count	1	47	48
	% within group	2.1%	97.9%	100.0%
Handsewn	Count	2	13	15
	% within group	13.3%	86.7%	100.0%
Total	Count	3	60	63
	% within group	4.8%	95.2%	100.0%

Table.18 Anastomotic Leak – SEMS

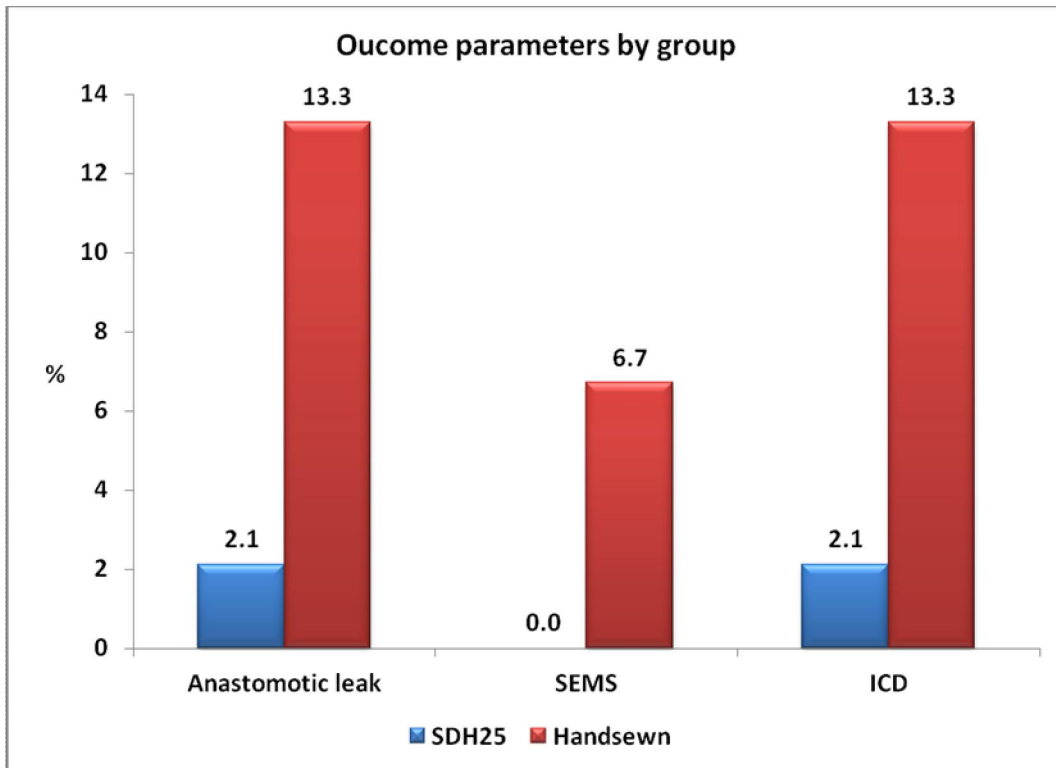
		SEMS		Total
		Yes	No	
SDH25	Count	0	48	48
	% within group	.0%	100.0%	100.0%
Handsewn	Count	1	14	15
	% within group	6.7%	93.3%	100.0%
Total	Count	1	62	63
	% within group	1.6%	98.4%	100.0%

One patient in hand sewn group with anastomotic leak had SEMS for partial disruption of oesophagojejunal anastomosis. None other anastomotic leak patients had SEMS. Which was not statistically significant with p value = 0.238.

Table.19 Anastomotic Leak – ICD

		ICD		Total
		Yes	No	
SDH25	Count	1	47	48
	% within group	2.1%	97.9%	100.0%
Handsewn	Count	2	13	15
	% within group	13.3%	86.7%	100.0%
Total	Count	3	60	63
	% within group	4.8%	95.2%	100.0%

All the three anastomotic leak patients were initially managed by ICD tube insertion. Which was not statistically significant with p value = 0.138.



Following ICD insertion one patient in handsewn group was managed by SEMS and one patient in stapler group was managed by relaparotomy.

Table.20 Wound Infection Rate				
		WI		Total
		Yes	No	
SDH25	Count	6	42	48
	% within group	12.5%	87.5%	100.0%
Handsewn	Count	5	10	15
	% within group	33.3%	66.7%	100.0%
Total	Count	11	52	63
	% within group	17.5%	82.5%	100.0%

Comparing the both groups 12.5% of stapler group patients and 33.3% of handsewn group patients had wound infections and it was not statistically significant with P value of 0.113.

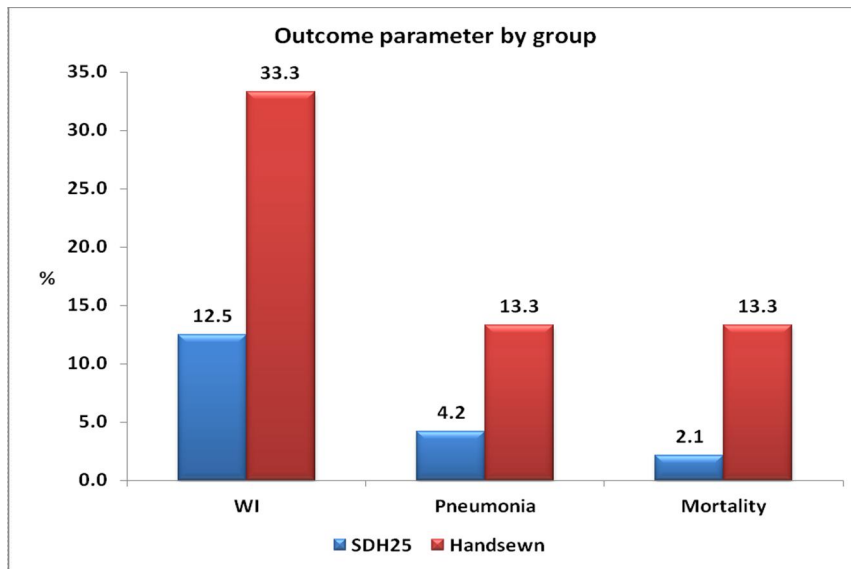


Table.21 Pneumonia Rate

		Pneumonia		Total
		Yes	No	
SDH25	Count	2	46	48
	% within group	4.2%	95.8%	100.0%
Handsewn	Count	2	13	15
	% within group	13.3%	86.7%	100.0%
Total	Count	4	59	63
	% within group	6.3%	93.7%	100.0%

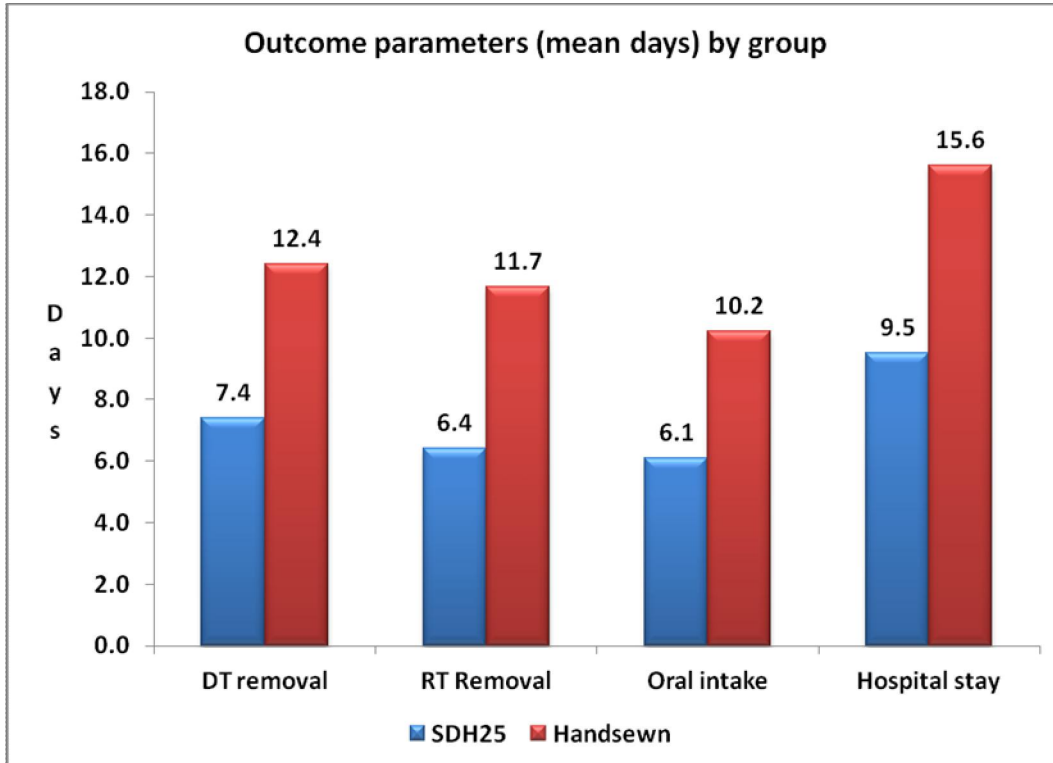
Comparing the both groups 4.2% of stapler group patients and 13.3% of handsewn group patients had pneumonia and it was not statistically significant with P value of 0.238.

RT Removal

Comparing the both groups mean RT removal on 6.42 day in stapler group and 11.67 day in hand sewn group which was statistically significant with p value=0.002.

Table.22 RT Removal

Group	N	Mean	Std. Deviation	P-value
RT Removal SDH25	48	6.42	2.431	0.002
Handsewn	15	11.67	5.192	



DT Removal

Comparing the both groups mean DT removal on 7.40 day in stapler group and 12.40 day in hand sewn group which was statistically significant with p value=0.001.

Table.23 DT Removal

Group	N	Mean	Std. Deviation	P-value
DT removal SDH25	48	7.40	2.295	0.001
Handsewn	15	12.40	4.437	

Oral intake

Comparing the both groups mean oral intake on 6.09 day in stapler group and 10.01 day in hand sewn group which was statistically significant with p value=0.000.

Table.24 Oral intake

Group	N	Mean	Std. Deviation	P-value
Oral intake SDH25	47	6.09	.803	0.000
Handsewn	14	10.21	1.847	

Hospital Stay

Comparing the both groups mean hospital stay 9.52 day in stapler group and 15.6 day in hand sewn group which was statistically significant with p value=0.000.

Table.25 Hospital Stay

Group	N	Mean	Std. Deviation	P-value
Hospital stay SDH25	48	9.52	2.163	0.000
Handsewn	15	15.60	3.757	

Table.26 Stricture Rate

		Stricture		Total
		Yes	No	
SDH25	Count	1	47	48
	% within group	2.1%	97.9%	100.0%
Handsewn	Count	1	14	15
	% within group	6.7%	93.3%	100.0%
Total	Count	2	61	63
	% within group	3.2%	96.8%	100.0%

Comparing the both groups Table.26 one patient (2.1%) in stapler group and one patient (6.7%) in handsewn group had stricture which was managed by endoscopic dilatation. Which was not statistically significant with p value = 0.422.

Table.27 Stricture - Dilatation

		Dilatation		Total
		Yes	No	
SDH25	Count	1	47	48
	% within group	2.1%	97.9%	100.0%
Handsewn	Count	1	14	15
	% within group	6.7%	93.3%	100.0%
Total	Count	2	61	63
	% within group	3.2%	96.8%	100.0%

Table.28 Margin Status

		Margin Positive		Total
		No	Yes	
SDH25	Count	47	1	48
	% within group	97.9%	2.1%	100.0%
Handsewn	Count	14	1	15
	% within group	93.3%	6.7%	100.0%
Total	Count	61	2	63
	% within group	96.8%	3.2%	100.0%

Comparing the both groups Table.28 one patient (2.1%) in stapler group and one patient (6.7%) in handsewn group had proximal margin positive for tumour which was not statistically significant with p value=0.422.

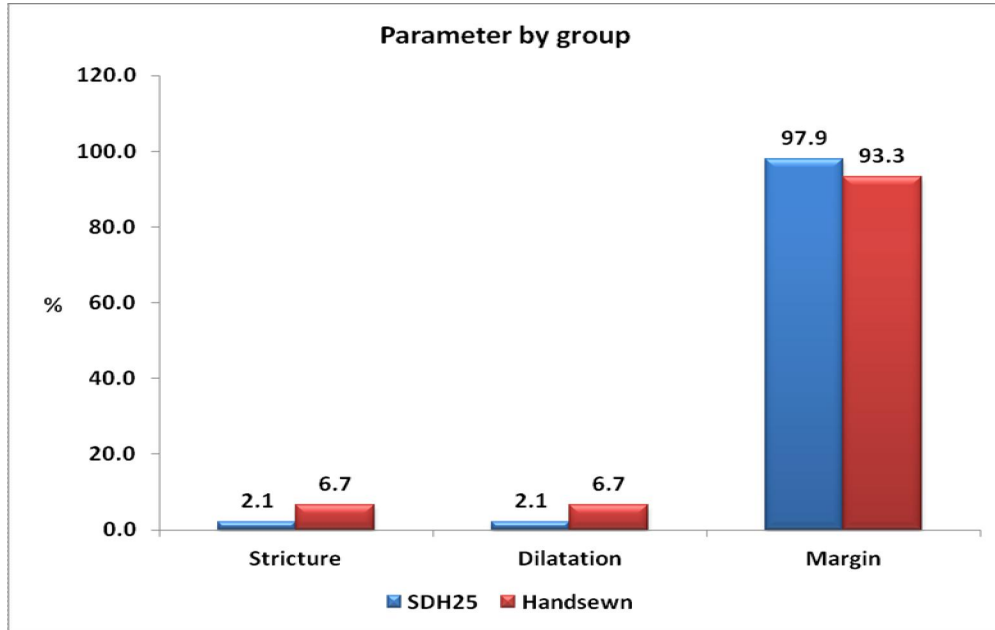


Table.29 Adjuvant Chemotherapy Status

		Adj.CT		Total
		Yes	No	
SDH25	Count	47	1	48
	% within group	97.9%	2.1%	100.0%
Handsewn	Count	13	2	15
	% within group	86.7%	13.3%	100.0%
Total	Count	60	3	63
	% within group	95.2%	4.8%	100.0%

All patients in both the groups had adjuvant chemotherapy except one who died in stapler group and two who died in handsewn group.

Which was not statistically significant with p value = 0.138.

Table.30 Recurrence Rate

		Recurrence		Total
		Yes	No	
SDH25	Count	1	47	48
	% within group	2.1%	97.9%	100.0%
Handsewn	Count	1	14	15
	% within group	6.7%	93.3%	100.0%
Total	Count	2	61	63
	% within group	3.2%	96.8%	100.0%

Comparing the both groups 97.9 % in stapler group and 93.3% in handsewn group had no tumour recurrence. One patient (2.1%) in stapler group and one patient (6.7%) in handsewn group had tumour recurrence which was not statistically significant with p value=0.422. They were managed by palliative chemoradiotherapy.

Table.31 Mortality Rate

		Mortality		Total
		Yes	No	
SDH25	Count	1	47	48
	% within group	2.1%	97.9%	100.0%
Handsewn	Count	2	13	15
	% within group	13.3%	86.7%	100.0%
Total	Count	3	60	63
	% within group	4.8%	95.2%	100.0%

Comparing the both groups the mortality in the patients who underwent stapled oesophagojejunal anastomosis was 2.1% and the mortality in the hand sewn oesophagojejunal anastomosis group was 13.3%. The overall mortality rate was 4.8%. Which was not statistically significant with p value = 0.138.

DISCUSSION

After total gastrectomy, Roux-en-Y esophagojejunal anastomosis is preferred by the majority of surgeons. The short term and long term postoperative morbidity and mortality after total gastrectomy were directly related to the esophagojejunal anastomosis, mainly anastomotic leakage that can lead to sepsis, and anastomotic stricture. So we studied short term and long term outcomes of stapled versus hand sewn oesophagojejunal anastomosis after total gastrectomy in our super specialty department and predicted the outcome, hence formulate a standard protocol for surgery.

An interest in comparing stapled and manual suture anastomosis has existed since the introduction of the first mechanical stapler¹². Studies by Fujimoto et al⁶ tried to show the lack of a significant difference between the two techniques, but the debate continued and some found marginally better outcomes for stapled anastomosis.⁷ Large studies from Japan's National Cancer Center from 1985 to 1997 showed a decrease in the rate of anastomotic leakage. Leakage rates as low as 0.5% for stapled anastomoses was reported¹³ and now stapled esophagojejunostomy is considered by most to be the best alternative.

Clinical Presentation

The commonest symptomatic presentation of OG junction and proximal gastric carcinoma was dysphagia, resulting from luminal narrowing at OG junction. Although some patients exhibit a vague abdominal pain, locally advanced cancer with tumor invasion of celiac plexus typically causes a constant dull pain accompanied by back pain. Non-specific symptoms such as nausea, anorexia, weight loss and fatigue are common in many patients. Significant weight loss of 10% or more is well known to affect outcome adversely with increased susceptibility to post op complication rate. In our study 87.3% of patients presented with dysphagia, 40% presented with abdominal pain, 97.4% presented with loss of appetite and loss of weight.

Co-morbid Illness and Nutritional Status

As many patients are elderly with co-morbid illness and complaints of dysphagia with poor nutritional intake leads to higher incidence of poor performance status. Weight loss and dehydration are frequent features in such patients and hence need to be aggressively addressed. Cardio pulmonary testing assesses the ability to deliver oxygen during stress and the need for postoperative ventilator support. So routine preoperative blood tests and careful history taking might help surgeons to identify high risk

patients and subject them for optimization before such major surgical procedure. In our study 5% had diabetes mellitus 3.2% hypertension.

Personal habits

Though dietary habits have no direct influence, they have indirect influence in the form of nutritional status and hence the performance status. Patients who were found to be nutritionally depleted were encouraged to take adequate enteral formulas and albumin infusion was administered preoperatively. Patients with significant morbidity related to pulmonary mechanism were all smokers. Hence abstinence of smoking for atleast 2 weeks before surgery, along with incentive spirometry, nebulisation with bronchodilators and mucolytics given preoperatively and continued post operatively. Aggressive postoperative chest physiotherapy and ventilator support if necessary were given to all smokers.

In our study 92% of patients were non-vegetarians, 8% were vegetarians, 49% smokers and 51% alcoholic. Dietary and personal habits are not having statistically significant outcome in our study.

Physical examination

In our study pallor was the commonest clinical presentation, was present in 70% of patients and abdominal mass was present in 4.8% of the total patients.

Imaging, Endoscopy and Biopsy

All patients underwent initial ultrasonogram of the abdomen and pelvis. Hence ultrasonogram is an easily available, cost effective, less time consuming and adequate initial imaging study to look for liver secondaries and ascites but the disadvantage is the observer variation which is operator dependent. Initially we did CECT for evaluation but now we are switching over to multi slice CECT to assess the resectability accurately. We have done upper GI endoscopy and biopsy for all patients before surgery.

Intraoperative Factors

Duration of surgery

There was a prolonged operative time (mean 208 mins) in hand sewn esophagojejunal anastomoses group when compared with the hand sewn esophagojejunal anastomoses group (171 mins) and which was statistically significant with p value=000. As our centre is a teaching institution where surgery is done by Professors, Assistant Professors and Post Graduates there is a wide variation in the duration of surgery and hence the morbidity.

Type of anastomosis and anastomotic leak

Among the complications oesophagojejunal anastomotic leak in stapler anastomosis group was present in 1 patient (2.1%) and in hand sewn anastomosis group were present in (13.3%). All the three anastomotic leak patients had ICD tube and one patient in hand sewn group with anastomotic leak had SEMS for partial disruption of oesophagojejunal anastomosis.

There are randomized controlled trials, has shown no difference between both subgroups in terms of leak as well as major morbidity.

Stapled anastomoses are saving the operating time and allow greater integrity upon the anastomosis, resulting in reduced morbidity and shorter hospital stay.

Another advantage of stapled anastomosis is that it allows higher anastomosis after radical total gastrectomy for OG junction carcinoma and proximal gastric carcinoma without thoracotomy, especially with tumors demonstrating intramural infiltration.

Margin

Proximal margin was positive in one case in each group which was not statistically significant, was managed by adjuvant chemotherapy.

CONCLUSION

Our study shows that:

In stapler group operative time and hospital stay were less and also statistically significant compared to hand sewn group.

Anastomotic leakage in stapler group was less but not statistically significant compared to hand sewn group.

RT removal, DT removal and post operative day of initiating oral intake were earlier and also statistically significant compared to hand sewn group.

The data support the use of stapled esophagojejunal anastomosis as a safe way to create an oesophagojejunal anastomosis, it is quick to perform allowing shorter operating time and hospital stay and does not appear to be associated with a previously noted increased incidence of benign anastomotic stricture formation when compared with handsewn anastomoses.

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APPENDIX

CASE RECORD FORM

Name: Age / Sex :

IP No:

DOA: DOS: DOD:

Education status :

Occupation :

Address & Contact Number:

Clinical History:

H/o difficulty in swallowing

H/o abdominal pain / back pain

H/o abdominal distension

H/o vomiting / Haematemesis / Malena / jaundice

H/o Loss of appetite / Loss of weight

H/o cough with expectoration

H/o difficulty in breathing

H/o smoking / alcohol intake / Veg. / Non- Veg

H/o DM, SHT, BA, TB, IHD

H/o upper G I surgery

Clinical Examination:

General examination: Pallor / Icterus / Pedal Edema

Abdominal examination: Palpable mass / Liver / Free Fluid

Per Rectal Examination: Malena / Pelvic Deposit

Respiratory system examination:

Cardiovascular system examination:

Investigations:

Complete blood count: Hb% TC DC ESR

Blood sugar

Renal function tests

Urea

Serum creatinine & electrolytes

Liver function tests

Bilirubin: TB DB

SGOT

SGPT

SAP

Serum albumin

Prothrombin time

ECG

Chest X-ray

USG abdomen & Pelvis

CECT abdomen & Chest:

Barium swallow

Upper GI endoscopy & Biopsy:

PROVISIONAL DIAGNOSIS:

Operation Details:

Operable / inoperable

Reasons for inoperability

Type of surgical Procedure

Type of Anastomosis after Total gastrectomy

Stapled / Hand sewn

Type of stapler

Type of reconstruction

Roux loop Y Oesophagojejunal Anastomosis

Duration of surgery

Blood Loss & Blood Transfusion:

Post op Details:

RT Removed on:

Postoperative day of initiating oral intake

Incidence of anastomotic leakage

Incidence of anastomotic stricture

Margin Status

In hospital stay

In hospital morbidity

Minor: Wound infection / Pneumonitis

Major: Anastomotic leak / Intra abdominal collection

In hospital mortality

Information to Participants

Title: SHORT TERM AND LONG TERM OUTCOMES OF STAPLED VERSUS HAND SEWN OESOPHAGOJEJUNAL ANASTOMOSIS AFTER TOTAL GASTRECTOMY

Principal Investigator:

Co-Investigator(if any):

Name of Participant:

Site :

You are invited to take part in this research/ study/procedures/tests. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

What is the purpose of research?

Trials comparing different anastomotic techniques have arrived at different conclusions. This study is to compare the short term and long term outcomes of stapled versus hand sewn esophagojejunal anastomoses after total gastrectomy for OG Junction carcinoma and proximal gastric carcinoma in our super specialty department, hence formulate a standard method of patient selection, type of anastomosis and perioperative care to achieve good outcome after total gastrectomy. We want to test the efficacy and safety of a new _____ (drug / intervention / surgery /procedure/lab test) in this disease/condition.

We have obtained permission from the Institutional Ethics Committee.

The study design

Retrospective study

Study Procedures

The study involves evaluation of SHORT TERM AND LONG TERM OUTCOMES OF STAPLED VERSUS HAND SEWN OESOPHAGOJEJUNAL ANASTOMOSIS AFTER TOTAL GASTRECTOMY. The planned scheduled visits involve visits at _____, _____, _____, and _____ (days/ weeks) after your initial visit. You will be required to visit the hospital _____ number of times during the study.

At each visit, the study physician will examine you. Some [blood / urine / other] tests will be carried out at each visit. [... .. ml of blood will be collected at each visit. Blood collection involves prick with a needle and syringe.] These tests are essential to monitor your condition, and to assess the safety and efficacy of the treatment given to you.

In addition, if you notice any physical or mental change(s), you must contact the persons listed at the end of the document.

You may have to come to the hospital (study site) for examination and investigations apart from your scheduled visits, if required.

Women of childbearing potential

You must not participate if you are pregnant, breastfeeding a child, or if you are of childbearing potential and not practicing effective methods of contraception **(for studies/procedures which may harm the fetus)**.

Possible risks to you – If any, Briefly mention**Possible benefits to you - If any, Briefly mention****Possible benefits to other people**

The results of the research may provide benefits to the society in terms of advancement of medical knowledge and/or therapeutic benefit to future patients.

Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, Institutional Ethics Committee and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

How will your decision to not participate in the study affect you?

Your decision not to participate in this research study will not affect your medical care or your relationship with the investigator or the institution. You will be taken care of and you will not lose any benefits to which you are entitled.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to stopping the treatment/discontinuing of procedures etc.

Signature of Investigator

Signature of Participant

date

date

ஆராய்ச்சி ஒப்புதல் கடிதம்

முழு இணைப்பை அகற்றலுக்குப்பின் இணைப்புக் கருவி மற்றும்
கைத் தையல் மூலம் உணவுக்குழாய் - முன் சிறுகுடல் இணைப்பின் குறுகிய
கால மற்றும் நீண்டகால விளைவுகள்

பெயர் : தேதி :
வயது : உள்/புறநோயாளி எண் :
பாலினம்: ஆராய்ச்சி சேர்க்கை எண் :

என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடன் இந்த
மருத்துவ ஆராய்ச்சியில் சேர்த்துக் கொள்ள ஒப்புதல் அளிக்கிறேன்.

கீழ்காணப்படும் நிபந்தனைகளுக்கு நான் ஒப்புதல் அளிக்கிறேன்.

இந்த ஆராய்ச்சியின் நோக்கமும், சிகிச்சை முறைகளும் எனக்கு
திருப்தியளிக்கும் வகையில் அறிவுறுத்தப்பட்டது.

உணவுக்குழாய் இரைப்பை இணைப்புப் பகுதி கட்டி மற்றும் இரைப்பை
கட்டியினால் ஏற்படும் அறிகுறிகள், எனக்கு மேற்கொள்ளப்படும் சிகிச்சை
முறைகள், அதனால் ஏற்படும் பின்விளைவுகள் அனைத்தையும் நான்
அறிவேன்.

என் உடல்நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு
மாறான நோய்க்குறி தென்பட்டாலோ அதனை உடனடியாக மருத்துவரிடம்
தெரிவிக்க சம்மதிக்கிறேன்.

என் மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக்
கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும், ஆராய்ச்சியாளரும்
என்னுடைய விவரங்கள் அனைத்தையும் இரகசியமாக வைப்பதாக அறிகிறேன்.

நோயாளியின் பெயர்

கையொப்பம்

தேதி

ஆராய்ச்சியாளரின் பெயர்

கையொப்பம்

தேதி

ஆராய்ச்சி தகவல் தாள்

முழு இணைப்பை அகற்றலுக்குப்பின் இணைப்புக் கருவி மற்றும்
கைத் தையல் மூலம் உணவுக்குழாய் - முன் சிறுகுடல் இணைப்பின் குறுகிய
கால மற்றும் நீண்டகால விளைவுகள்

பங்கேற்பாளர் பெயர் :
ஆராய்ச்சியாளர் பெயர் :

சென்னை இராஜீவ்காந்தி அரசு பொது மருத்துமனையில் அனுமதி பெரும் உணவுக்குழாய் இரைப்பை இணைப்புப் பகுதி புற்றுநோய் கட்டி மற்றும் இரைப்பை புற்றுநோய் கட்டி உள்ள நோயாளிகள் பற்றிய ஆராய்ச்சி இங்கு நடைபெற்று வருகின்றது.

இந்த புற்று கட்டியினால் உணவுக்குழாயில் அடைப்பு ஏற்பட்டு, விழுங்குவதில் கஷ்டம் ஏற்படுகிறது. இந்த புற்று கட்டியை முழுவதுமாக இரைப்பையுடன் சேர்த்து அகற்றிவிட்டு உணவுக்குழாயை முன் சிறுகுடலுடன் இணைப்புக் கருவி / கை தையலால் இணைத்து வைக்கப்படும்.

நீங்களும் ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் உங்களுக்கு நடைபெறும் சிகிச்சை முறைகள் மற்றும் அதன் விளைவுகள் பற்றிய ஆராய்ச்சி செய்ய உள்ளோம். இதனால் உங்களது உடல்நலமோ, மனநலமோ பாதிக்கப்படாது.

முடிவுகளை அல்லது கருத்துகளை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின்பேரில் தான் இருக்கிறது. மேலும், நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின் வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்பு அறுவைசிகிச்சையின் பலன்களை /முடிவுகளை ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின்போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம்

தேதி:

பங்கேற்பாளர் கையொப்பம்

தேதி:

MASTER CHART

S.N o	Age	Sex	IP No.	Abd pain	Dysphagia	N&V	Hematemesis	Male	LOA / LOW	D M	SH T	Smoking	Alcohol	Non-Veg / Veg	Pallor	Abd Mass	Hb	Alb	OGD & Bx	CECT Abd	Ca. OGD / PGCA	Stage / 3	Adj. T	TG	Adeno Ca	Duratin (Mins)	Bld Loss	Bld Tr	SDH 25 / Hand sewn	R0 / R1	Anasto molti Leak	SEMS	RT Removal	ICD	DT Removal	Oral intake	Stricture	Dilatn	Wl	Pneu	Hospital stay	Recurrance	Mortality
1	50	F	55973	2	1	2	2	2	1	2	2	2	2	1	2	9.5	3.2	1	1	2	2	1	1	1	180	200	2	1	1	2	2	6	2	7	6	2	2	2	2	2	9	2	2
2	35	fm	70656	1	2	2	2	1	2	2	1	1	1	1	2	8	3.1	1	1	2	2	1	1	1	210	250	1	2	1	2	2	10	2	11	10	2	2	1	2	14	2	2	
3	62	F	81653	2	1	1	1	1	1	2	2	2	1	1	2	7	3	1	1	2	2	2	1	1	180	200	1	1	2	2	22	1	22	NS	2	2	1	1	22	1	1		
4	65	F	57953	2	1	1	2	2	1	2	1	2	2	1	2	11	4.2	1	1	2	2	1	1	1	180	200	2	1	1	2	2	7	2	8	7	2	2	2	2	10	2	2	
5	51	fm	85798	1	1	1	1	1	1	2	1	1	1	1	2	7	2.5	1	1	2	2	1	1	1	180	200	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
6	40	fm	90139	2	2	2	1	1	2	2	1	1	1	1	2	7	3.1	1	1	2	2	1	1	1	200	220	1	2	1	2	2	10	2	11	10	2	2	1	2	15	2	2	
7	49	F	65638	2	1	1	1	1	1	2	2	2	1	1	2	6.8	2.9	1	1	1	2	1	1	1	180	200	1	1	1	2	2	7	2	8	7	2	2	2	2	10	2	2	
8	65	fm	92277	2	1	2	2	2	1	2	2	1	1	1	2	12	4.2	1	1	1	1	1	1	1	210	180	2	2	1	2	2	10	2	11	10	1	1	1	1	18	2	2	
9	65	F	93143	1	2	2	2	1	2	2	2	2	2	1	1	4.9	2.9	1	1	2	2	1	1	1	220	250	1	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
10	55	fm	98415	2	1	1	1	1	1	2	2	1	1	1	1	5.4	2.9	1	1	1	1	1	1	1	180	200	1	1	1	2	2	6	2	7	6	2	2	2	2	10	2	2	
11	64	fm	98755	2	1	2	2	1	1	2	2	1	1	1	1	6	3.1	1	1	2	2	1	1	1	160	200	1	1	1	2	2	7	2	8	7	2	2	2	2	10	2	2	
12	58	fm	98870	1	1	2	2	2	1	2	2	1	1	1	2	13	4.2	1	1	1	1	1	1	1	210	180	2	2	1	2	2	7	2	8	7	2	2	2	2	14	2	2	
13	40	F	14339	2	1	1	1	1	1	2	2	2	1	1	2	7.9	3.4	1	1	2	2	1	1	1	160	180	1	1	1	2	2	7	2	8	7	2	2	2	2	10	2	2	
14	52	fm	11823	1	1	2	2	1	1	2	2	1	1	1	2	6.9	3.2	1	1	2	2	1	1	1	150	180	1	1	1	2	2	7	2	8	7	2	2	1	2	10	2	2	
15	26	F	23336	2	1	1	1	1	1	2	2	2	1	1	2	7	3.1	1	1	1	1	1	1	200	180	1	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2		
16	61	fm	40372	2	2	2	2	1	2	2	1	1	1	2	2	14	4.2	1	1	2	2	1	1	1	210	180	2	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
17	40	F	70477	1	1	2	2	1	1	2	2	2	1	1	2	7	3.1	1	1	1	2	1	1	1	160	110	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
18	57	fm	78530	2	1	2	2	2	1	2	2	2	1	1	2	9	3.2	1	1	2	2	2	1	1	220	250	1	2	2	1	1	27	1	25	16	2	2	1	1	27	1	1	
19	50	F	76215	2	1	2	2	2	1	2	2	2	1	2	2	11	3.9	1	1	2	2	2	1	1	160	110	2	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
20	60	fm	82405	2	1	1	1	1	1	2	2	1	1	1	1	5.5	2.8	1	1	2	2	1	1	1	180	250	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
21	35	fm	106219	1	2	2	2	1	1	2	2	1	1	1	1	7	3.1	1	1	2	2	1	1	1	160	110	1	1	1	2	2	5	2	6	5	2	2	2	2	9	2	2	
22	63	fm	94030	2	1	2	2	2	1	2	2	1	1	1	2	8	3.1	1	1	2	2	1	1	1	140	110	1	1	1	2	2	5	2	6	5	2	2	2	2	9	2	2	
23	55	fm	111635	1	2	2	2	2	2	2	1	1	2	2	2	12.8	4.2	1	1	2	2	1	1	1	210	180	2	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
24	54	fm	43527	2	1	2	2	1	1	2	2	1	1	1	2	9	3.1	1	1	1	1	1	1	1	160	110	2	1	1	2	2	6	2	7	6	2	2	2	2	10	2	2	
25	35	fm	52328	1	1	2	2	1	1	2	2	2	1	1	2	8	3.1	1	1	2	2	1	1	1	200	180	1	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
26	54	F	60985	2	1	2	2	2	1	2	2	2	1	2	2	11.4	4.2	1	1	2	2	2	1	1	160	120	2	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
27	39	F	61365	1	1	2	2	2	1	2	2	2	1	1	2	9	3.7	1	1	2	2	1	1	1	160	120	2	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
28	50	F	87679	2	1	1	2	1	1	2	2	2	1	1	2	7	3.1	1	1	2	2	2	1	1	190	200	1	2	1	1	21	1	21	NS	2	2	1	1	21	2	1		
29	27	F	93947	1	1	2	2	2	1	2	2	2	1	2	2	12.6	4.2	1	1	2	2	1	1	1	180	200	2	1	1	2	2	7	2	8	7	2	2	2	2	10	2	2	
30	60	fm	102396	2	1	1	1	1	1	2	2	1	1	1	2	7	2.9	1	1	1	2	1	1	1	190	200	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
31	60	F	51508	1	2	2	2	1	2	2	2	2	1	2	2	6	2.8	1	1	2	2	1	1	1	180	200	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
32	35	F	28248	2	1	1	2	2	1	2	2	2	1	2	2	10	3.9	1	1	2	2	2	1	1	160	120	2	1	1	2	2	5	2	6	5	2	2	2	2	8	2	2	
33	64	fm	109367	2	1	2	2	2	1	2	2	1	1	1	2	9	3.9	1	1	2	2	1	1	1	210	180	2	2	1	2	2	10	2	11	10	2	2	2	2	13	2	2	
34	66	fm	54976	1	1	2	2	1	1	2	2	1	1	1	2	7	3.1	1	1	2	2	1	1	1	200	180	1	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
35	70	fm	73234	2	1	2	2	1	1	2	2	1	1	1	2	8	3.1	1	1	2	2	1	1	1	220	220	1	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
36	53	F	55663	1	1	2	2	1	1	2	2	2	1	1	2	7	3.2	1	1	2	2	1	1	1	180	200	1	1	1	2	2	7	2	8	7	2	2	1	2	10	2	2	
37	53	fm	70565	2	1	2	2	1	1	2	2	1	1	1	2	8	3.1	1	1	2	2	1	1	1	210	180	1	2	1	2	2	10	2	11	10	2	2	2	2	14	2	2	
38	42	F	60653	2	1	2	2	2	1	2	2	2	1	2	2	12	4.2	1	1	2	2	1	1	1	180	200	2	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
39	56	F	56379	2	1	2	2	1	1	2	2	2	1	1	2	7.2	3.2	1	1	2	2	1	1	1	180	200	1	1	1	2	2	6	2	7	6	2	2	1	2	9	2	2	
40	49	fm	75898	1	1	2	2	2	1	2	2	1	1	1	2	7.8	3.2	1	1	2	2	2	1	1	180	200	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
41	40	fm	90931	2	1	1	1	1	1	2	2	2	1	1	2	6	3.2	1	1	2	2	1	1	1	190	200	1	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
42	59	F	63658	1	1	1	2	1	1	2	2	2	1	1	2	8	3.2	1	1	1	1	1	1	1	180	200	1	1	1	2	2	6	2	7	6	2	2	1	2	10	2	2	
43	65	fm	98514	2	1	2	2	2	1	2	2	1	1	1	2	9	3.9	1	1	1	2	1	1	1	180	200	2	1	1	2	2	6	2	7	6	2	2	2	2	9	2	2	
4																																											

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To

Dr.C.Kolandasamy,
M.Ch Post Graduate,
Department of Surgical Gastroenterology & Proctology,
Madras Medical College & RGGGH, Chennai -3

Dear Dr.C.Kolandasamy,

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "Short term and Long term outcomes of Stapled versus Hand Sewn Oesophagojejunal Anastomosis after Total gastrectomy" No.15022013.

The following members of Ethics Committee were present in the meeting held on 05.02.2013 conducted at Madras Medical College, Chennai -3.

- | | |
|---|---------------------|
| 1. Dr.SivaKumar, MS FICS FAIS | --- Chairperson |
| 2. Prof. R. Nandhini MD
Director, Instt. of Pharmacology ,MMC, Ch-3 | -- Member Secretary |
| 3. Prof. Shyamraj MD
Director i/c , Instt. of Biochemistry , MMC, Ch-3 | -- Member |
| 4. Prof. P. Karkuzhali. MD
Prof., Instt. of Pathology, MMC, Ch-3 | -- Member |
| 5. Prof. A. Radhakrishnan MD
Prof of Internal Medicine, MMC, Ch-3 | -- Member |
| 6. Prof. S. Deivanayagam MS
Prof of Surgery, MMC, Ch-3 | -- Member |
| 7. Thiru. S. Govindsamy. BABL | -- Lawyer |
| 8. Tmt. Arnold Soulina MA MSW | -- Social Scientist |

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nedi 22/2/13
Member Secretary, Ethics Committee



Turnitin Originality Report

**SHORT TERM AND LONG TERM
OUTCOMES OF STAPLED VERSUS HAND
SEWN OESOPHAGOJEJUNAL
ANASTOMOSIS AFTER TOTAL
GASTRECTOMY** by Kolandasamy
Chinnusamy 18103503 M.Ch. Surgical
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