Short-Term Outcomes Of Single-Incision Distal Gastrectomy And Conventional Totally Laparoscopic Distal Gastrectomy - A Randomized Controlled Trial

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COI Disclosure

- The authors have no conflict of interest to disclose.

Introduction

- Single-incision distal gastrectomy (SIDG), first reported in 2011, is now more feasible due to technical advances in minimally invasive surgery.
- In a previous study, SIDG for treatment of early gastric cancer (EGC) offers possible benefits such as less postoperative pain and better cosmesis without increasing short-term complications.
- SIDG is being performed for select patients clinically diagnosed with EGC.

Purpose

- This study evaluates the postoperative outcomes and patient quality of life (QOL) of SIDG compared to conventional totally laparoscopic distal gastrectomy (TLDG).

Methodology

- Prospective Randomized Controlled Trial
- Inclusion criteria
  - Gastric adenocarcinoma at lower 2/3rds of the stomach, cT1N0M0
  - No previous treatment of gastric cancer excluding ESD
  - No previous history of other cancer
- Exclusion criteria
  - Operation other than distal gastrectomy
  - Open conversion

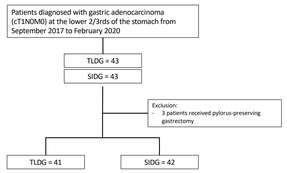
Methodology

- Primary endpoint: POD#1 VAS score (maximal)
- Sample size calculation
  - According to previously published data, VAS on POD#1 = 4.55 ± 1.04 vs 5.49 ± 1.39 ($p < 0.001$)

Target Power	Actual Power	N1	N2	N	μ1	μ2	δ	σ1	σ2	r
0.8	0.80252	34	34	68	4.6	5.5	-0.9	1	1.4	1

  - Estimated sample size: 34 in each group
  - Regarding drop-out ratio 20%, final sample size: 43 in each group
- Secondary endpoints: operation outcome, early morbidity and mortality, patient QOL using EORTC C30, STO22

Patient Flowchart



Results

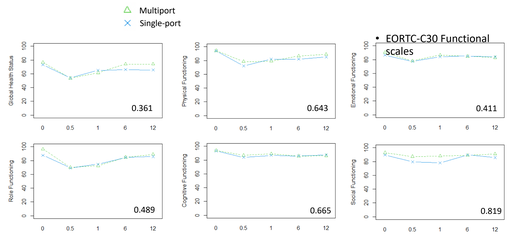
	TLDG (N=41)	SIDG (N=42)	p-value
Age (years)	58.9 ± 12.8	62.1 ± 9.7	0.192
Sex			1.000
Male	29 (70.7%)	29 (69.0%)	
Female	12 (29.3%)	13 (31.0%)	
Body mass index (kg/m2)	24.4 ± 3.5	24.3 ± 2.8	0.901
ASA score			
0	9 (22.0%)	11 (26.2%)	
1	26 (63.4%)	27 (64.3%)	0.725
2	5 (12.2%)	4 (9.5%)	
3	1 (2.4%)	0 (0.0%)	
History of abdominal operations			0.534
No	32 (78.0%)	36 (85.7%)	
Yes	9 (22.0%)	6 (14.3%)	
Reconstruction type			
Billroth I	18 (43.9%)	16 (39.0%)	
Billroth II	10 (24.4%)	12 (29.3%)	0.960
Roux-en Y	10 (24.4%)	10 (24.4%)	
Uncut Roux-en Y	3 (7.3%)	3 (7.3%)	
Lymph node dissection			
D1+	26 (63.4%)	19 (45.2%)	0.149
D2	15 (36.6%)	23 (54.8%)	

	TLDG (N=41)	SIDG (N=42)	p-value
Tumor size (cm)	2.6 ± 1.9	2.5 ± 1.5	0.811
Proximal margin (cm)	3.9 ± 2.3	3.7 ± 2.3	0.676
Distal margin (cm)	5.2 ± 2.5	4.6 ± 2.7	0.315
Retrieved number of LNs	63.2 ± 28.3	54.7 ± 19.7	0.121
pT stage			
pT1a	29 (72.5%)	27 (64.3%)	0.364
pT1b	10 (25.0%)	15 (35.7%)	
pT4a	1 (2.5%)	0 (0.0%)	
pN stage			
pN0	35 (87.5%)	38 (90.5%)	
pN1	3 (7.5%)	4 (9.5%)	0.528
pN2	1 (2.5%)	0 (0.0%)	
pN3b	1 (2.5%)	0 (0.0%)	

Results

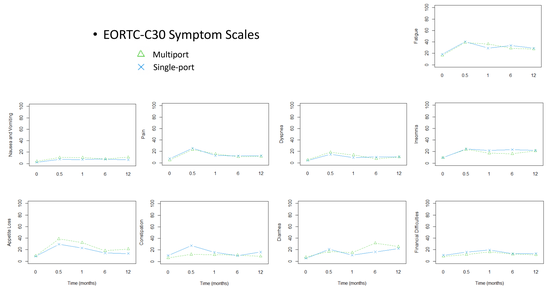
	TLDG (N=41)	SIDG (N=42)	p-value
Operative time (mins.)	154.2 ± 52.6	148.8 ± 50.7	0.636
Estimated blood loss (ml)	21.2 ± 32.0	11.0 ± 17.8	0.078
Time to first soft fluid diet (POD)	2.3 ± 0.7	2.1 ± 0.3	0.121
Time to first flatus (POD)	3.2 ± 0.9	3.0 ± 1.0	0.437
Hospital stay (days)	6.2 ± 2.2	6.3 ± 2.8	0.872
CRP levels at postoperative day 2 (mg/L)	11.9 ± 6.3	12.4 ± 5.3	0.716
POD#1 VAS Score	3.4 ± 0.8	3.3 ± 0.7	0.451
Early complication (≤ POD#30)	11 (26.8%)	8 (19.0%)	0.560
Early complication ≥ Clavien-Dindo Grade III	1 (2.4%)	1 (2.4%)	
Mortality	0 (0.0%)	0 (0.0%)	

- EORTC-C30 Function Scales

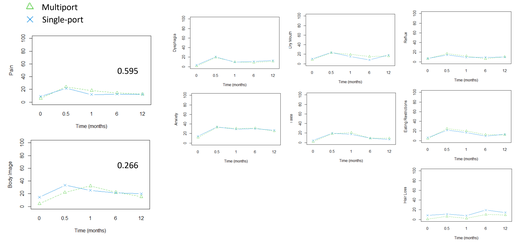


- EORTC-C30 Functional scales

- EORTC-C30 Symptom Scales



- EORTC-STO22 Symptom Scales



Conclusion

- There was no difference in early postoperative pain between SIDG and TLDG.
- SIDG did not increase short-term morbidity compared to TLDG.

