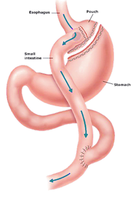
Onco-metabolic Surgery:
Comparison of the effect between long-limb and conventional Roux-en Y reconstruction after subtotal gastrectomy in gastric cancer patients with type II diabetes

Jong-Han Kim, department of foregut surgery, Korea University College of Medicine

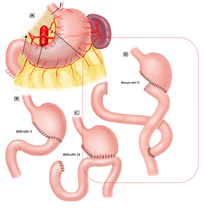
Diabetes & gastric cancer

Reconstruction methods after gastric cancer surgery

Standard RYGB
Roux limb 100cm, BPL 50cm



Roux-en-Y after Distal Gastrectomy
Roux limb 40cm, BPL 20cm

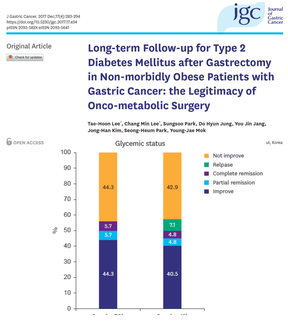


Primary Endpoint

- **Rate of more than improvement in diabetic control**
  - **HbA1c <6.5%, FBS 125 mg/dL & not increase in antidiabetic medication requirement**

◆Defintion of improvement of diabetic control (ADA):

1. **Improvement** was defined that reduction in HbA1c and FBS not meeting criteria for remission but decrease in antidiabetic medications requirement
2. **Partial remission** was defined sub-diabetic hyperglycemia (FBS 100-125 mg/dL & HbA1C 6-6.4%) in the absence of antidiabetic medications
3. **Complete remission** was defined that normal measures of glucose metabolism (HbA1c <6%, FBS<100 mg/dL) in absence of antidiabetic medications



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Glycemic control at 2 & 5 years

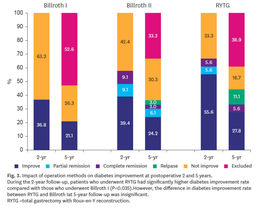


Fig. 3. Impact of operation methods on diabetes improvement at postoperative 2 and 5 years.
During the 5-year follow-up, patients who underwent RYTG had significantly higher diabetes improvement rate compared with those who underwent Billroth I (P=0.035).However, the difference in diabetes improvement rate between RYTG and Billroth Ist 5-year follow-up was insignificant.
RYTG =total gastrectomy with Roux-en-Y reconstruction.

KLASS-09

Efficacy of onco-metabolic surgery

To investigate the effect of long-limb Roux-en-Y reconstruction after gastrectomy in gastric cancer patients with type II diabetes compared to the conventional Roux-en-Y reconstruction

✓Multicenter, prospective, randomized controlled trial

✓Investigator-Initiated Trial (IIT)

✓Supported by KLASS group

Study design

Prospective Randomized Controlled Trial
Multicenter (KLASS group)
IIT (Investigator Initiative Trial)

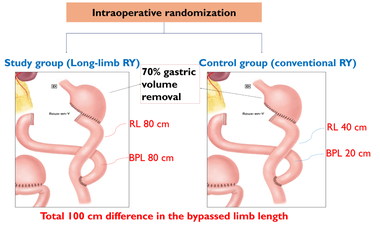
Clinical Stage I Gastric Cancer (≤80 years old)
Dx of Type 2 Diabetes
Preoperative BMI ≥ 23 kg/m²

Intraoperative Randomization

Study group: TLDG with Long Limb RY

Control group: TLDG with RY

Surgical procedures



Primary effective variable of this study
: Rate of HbA1c < 6.5% at postoperative 1 year

Enrollment ratio 1:1

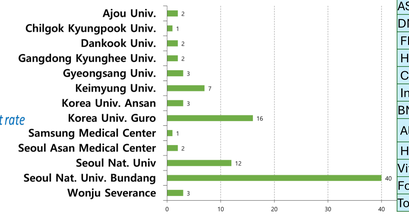
Expected difference in rates of HbA1c < 6.5%
: 70% in long-limb group vs. 40% in control group → *30% difference in improvement rate*

level of significance as 5%, power of test as 80%, dropout rate of 10 %

→ 94 in total (47 per each group)

KLASS-09 Progress

- 13 institutions
- 2022. Nov. N = 94 (100 %) registered

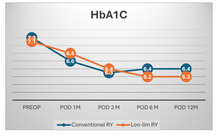


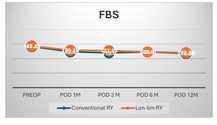
Enrolled patient's characteristics & data

	Conventional RY (N=46)	Long-limb RY (N=47)	p-value
Sex (M/F)	Jun-40	34/13	0.08
Age (yr, mean)	61.67±8.73	60.60±9.82	0.667
ASA (I/II/III)	12/29/5	11/34/2	0.424
DM duration (yr,mean))	6.5±7.1	7.4±6.9	0.582
FBS (mg/dl, mean)	141.38	138.7	0.716
HbA1C (%,mean)	7.282	7.208	0.821
C-peptide (ng/mL, mean)	3.55	2.41	0.192
Insulin (mg/dL, mean)	19.86	9.49	0.212
BMI (kg/m2, mean)	27.73	27.56	0.785
Albumin (g/dL, mean)	4.45	4.49	0.386
Hb (mg/dl, mean)	14.15	14.55	0.197
Vit B12 (pg/mL, mean)	700.07	759.46	0.787
Folate (ng/mL, mean)	11.42	11.61	0.767
Total chol (mg/dL/mean)	166.1	161.02	0.555

DM control variables preop & 12 months after surgery

	Conventional RY (N=46)		Long-limb (N=47)		P_Value
	MEAN	STD	MEAN	STD	
HbA1c					
PREOP	7.2	1.46	7.1	1.36	0.664
POD 1 M	6.6	0.83	6.84	0.94	0.198
POD 3 M	6.3	0.67	6.4	0.79	0.572
POD 6 M	6.4	0.77	6.2	0.93	0.209
POD 12M	6.4	0.68	6.2	0.88	0.886
FBS					
PREOP	141.83	46.46	143.89	47.73	0.834
POD 1 M	123.69	31.47	129.19	26.46	0.476
POD 3 M	119.9	18.9	127.85	27.13	0.117
POD 6 M	123.1	25.94	123.49	31.74	0.951
POD 12M	118.09	19.75	120.82	29.02	0.609





Nutritional factors

	Conventional RY (N=46)		Long-limb (N=47)		P_Value
	MEAN	STD	MEAN	STD	
BMI					
PREOP	27.73	3.1	27.57	3.31	0.803
POD 1 M	25.9	2.92	25.58	3.01	0.63
POD 3 M	25.84	3.27	25.38	2.67	0.514
POD 6 M	25.07	3.04	25.21	2.83	0.841
POD 12 M	25.18	3.32	25.31	3.04	0.871
Albumin					
PREOP	4.49	0.51	4.43	0.54	0.581
POD 1 M	4.31	0.29	4.23	0.29	0.22
POD 3 M	4.29	0.51	4.26	0.44	0.735
POD 6 M	4.19	0.45	4.3	0.46	0.265
POD 12 M	4.38	0.54	4.49	0.51	0.346

Glycemic control outcomes 1, 3, 6 & 12 M after surgery

	Conventional RY (N=46)		Long-limb RY (N=47)		P_Value
	N	%	N	%	
DM statue (1M)					0.568
Unchanged	13	31.7	14	31.1	
Improvement/partial/complete remision	19/8/1	68.3	24/7/0	68.9	
DM statue (3M)					0.259
Unchanged	8	17.8	12	25.5	
Improvement/partial/complete remision	20/15/2	82.2	22/13/0	74.5	
DM statue (6M)					0.11
Unchanged	20	46.5	9	20.9	
Improvement/partial/complete remision	11/10/2	53.5	21/8/5	79.1	
DM statue (12M)	43		42		0.029*
Unchanged	22	50	13	28.3	
Improvement/partial/complete remission	10/9/3	50	18/10/5	71.7	

What we can expect from KLASS-09 trial

- **Simultaneous control of gastric cancer & type 2 diabetes**
- **Correlation between diabetes control & length of small bowel bypass**
- **Efficacy of metabolic surgery in non-morbidly obese population**