

Chairperson(s): Jeong Min Lee *Seoul National University Hospital, Korea*

연구자 주도 외과 다기관 임상시험의 예

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KLASS 01 Trial

- Comparison LADG with ODG in Early Gastric Cancer-

Hyung-Ho Kim

Principal Investigator of KLASS 01 Trial
Department of Surgery
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Gastric Cancer

Current status as a major health problem

- ✓ 4th most common malignancy & 2nd cause of cancer death in the world
 - new patients : 988,000 / year, cancer death : 736,000 / year in 2008
- ✓ Most common cancer in Korea
 - new patients : 25,000 / year, cancer death : 10,000 / year in 2009
- ✓ Recently, the increased proportion of EGC
 - nearly 57.6% in Korea

<http://globocan.iarc.fr/factsheets/cancers/stomach.asp>
<http://www.cancer.go.kr/cms/statistics/incidence/index.html#4>
Oh Jeong et al. 2011. J Gastric Cancer.

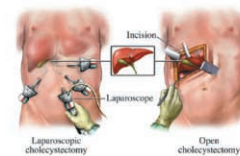
Gastric Cancer

The paradigm changes of gastric treatments

- ✓ Minimally Invasive Surgery (MIS) for gastric cancer
 - At present, becoming dominant position in EGC

1. Endoscopic resection
2. Laparoscopic gastrectomy + SNNS
3. Robotic surgery
4. Single-port surgery
5. Natural orifice transluminal endoscopic surgery (NOTES)

Laparoscopic Surgery



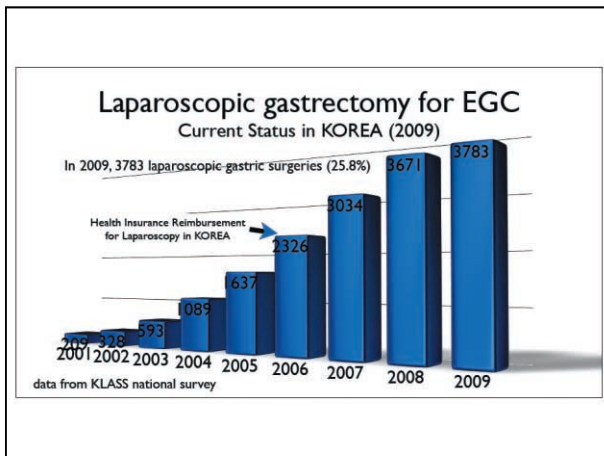
- ✓ 1987 Laparoscopic Cholecystectomy by Philippe Mouret et al.
 - Standard Operation in GB benign disease
 - ➡ Translation across the several range of abdominal surgery

Laparoscopic Gastrectomy for EGC

Laparoscopic Gastrectomy

History

1. 1992 Goh (Singapore) LAG with BI - Benign gastric ulcer
2. 1992 Ohgami (Japan) EGC - Lap. wedge resection & Intra gastric mucosal resection
3. 1994 Kitano (Japan) EGC - LADG with BI
4. 1996 HH Kim 1st LADG for EGC in Korea



Laparoscopic gastrectomy for distal EGC Evidences from Retrospective Studies

- Excellent short-term outcomes
- Good preserved immune function
- Less postoperative pain
- Rapid recovery of bowel function
- Better cosmesis
- Shorter hospital stay
- Less inflammatory reaction
- Rapid return to society

Hwang SH et al. Surg Endosc. 2009; Lee JH et al. Surg Endosc. 2009
Kitano et al. Ann Surg. 2007; Hwang SH et al. Arch Surg. 2009

Six Prospective RCTs about LADG for EGC

Author et al. Year	No. of Pts. FIU periods (mon)		Indication	LND		No. of Retrieved LNs		P-value	Recurrence or 5-year OS		P-value
	LADG	ODG		LADG	ODG	LADG	ODG				
Kitano et al. 2002	14 / 24.3±9.6	14 / 18.8±12.4	cT1	D1+0	20.2	24.9	NS	No Recurrence	No Recurrence	NS	
Lee JH et al. 2005	24 / med 14	23 / med 14	cT1	D2	31.8	38.1	NS	No Recurrence	No Recurrence	NS	
Hayashi et al. 2005	14 / 39(5-49)	14 / 45(34-53)	cT1	D1+0	28.0	27.0	NS	No Recurrence	No Recurrence	NS	
Huscher et al. 2005	30 / 52.2±26.5	29 / 49.7±5.2	T1-4	D1,2	30.0	33.4	NS	58.9%	55.7%	NS	
Kim YW et al. 2008	82 / ± 12	82 / ± 12	cT1	D1+R, D2	39.0	45.1	0.003	No Recurrence	No Recurrence		
Kim HH et al. 2010	179	163	≤cT2N0	D1+R, D2	-	-	-	-	-	-	

Laparoscopic gastrectomy for distal EGC We need Level I Evidences!!

- Level 1 evidences : Prospective, Randomized, Controlled (RCT)
- Level 2 evidences : Prospective, Controlled Trials ± Randomization (no.1)
- Level 3 evidences : Other Experimental & Non-experimental data
- Level 4 evidences : Expert opinion.

Laparoscopic colectomy for colon cancer
Level I evidences from COST trial

Laparoscopic Surgery for gastric cancer
No Level I evidences at present

But we expect that the long-term results of KCLASS trial will do the same in 2015

KCLASS

KLASS 01 Trial

Korean Laparoscopic Gastro-Intestinal Surgery Study Group

Investigator-Initiated surgical Trial (IIT)
19 surgeons from 16 centers

Retrospective cohort : 3284
Prospective cohort : 1415

Phase I Feasibility (retrospective)

- Case-control study : 3284 (1799 open vs. 1485 LAG) (1998.4~2005.12)
- Retrospective evaluation for short and long-term result
- Background data for Phase III

Phase II Morbidity and Mortality by Interim Analysis (RCT)

- Prospective randomized study : 342 cases
- Safety check of Phase III
- Morbidity and mortality of laparoscopic gastrectomy versus open gastrectomy for gastric cancer : An interim report (2006.1 ~2007.7)

Phase III Comparison LADG with ODG (RCT)

- Prospective randomized study : 1415 cases
- Comparison of long-term survival between LADG and ODG
- 2006.1 ~ 2014.5

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KLASS

Phase I
Demographics (n=3284)

Characteristics	OG (n=1799)	LAG (n=1495)	p
Age	58.8 ± 12.0	57.7 ± 12.1	0.006
Sex (M : F)	1252 : 547	932 : 553	< 0.001
Type of Procedure			< 0.001
DG	1251 (70.6%)	1325 (89.2%)	
TG	500 (28.2%)	130 (8.8%)	
PG	13 (0.7%)	24 (1.6%)	
PPG	3 (0.2%)	5 (0.3%)	
Others	6 (0.3%)	1 (0.1%)	
LND			< 0.001
< D2	309 (17.8%)	658 (44.3%)	
≥ D2	1425 (82.2%)	827 (55.7%)	
No. of retrieved LN	39.5 ± 17.0	31.7 ± 13.5	
Mortality	24 (1.3%)	9 (0.6%)	0.037

KLASS, Unpublished data

KLASS

Phase I
7th TNM Stage

Stage	OG (n=1799)	LAG (n=1495)	p
Ia	490 (27.2%)	1140 (76.8%)	<0.001
Ib	186 (10.3%)	158 (10.6%)	
IIa	181 (10.1%)	78 (5.3%)	
IIb	214 (11.0%)	64 (4.3%)	
IIIa	181 (10.1%)	12 (0.8%)	
IIIb	209 (11.6%)	0 (0%)	
IIIc	336 (18.7%)	33 (2.2%)	

KLASS, Unpublished data

KLASS

Phase I
Short-term outcomes of LAG

Variables	Value
Hospital Stay	8.7 ± 3.8
Time to Diet	4.6 ± 4.2
Complications	195 (13.7%)
Conversion to open surgery	3 cases*
Postoperative mortality	9 cases (0.6%)

* Diffuse oozing, Lesser sac hematoma, Mesocolon injury

KLASS, Unpublished data

KLASS

Phase II
Safety Verification of KLASS trial

Comparing Morbidity and Mortality Between LADG and ODG for EGC

- 342 Cases (2006.1 ~ 2007.7)
- Sample Size : Each group 163 (*Morbidity 17% / Power 0.8)
- LADG : ODG = 179 : 163
- M:F = 227:115 (2:1), Mean Age = 55.8

* Park DJ et al. Br J Surg. 2005;92(9):1099-1102
Kim HH & KLASS. Ann Surg. 2010;251:417-420

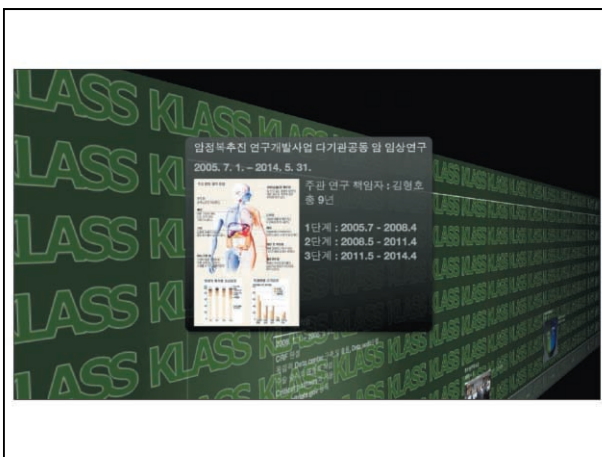
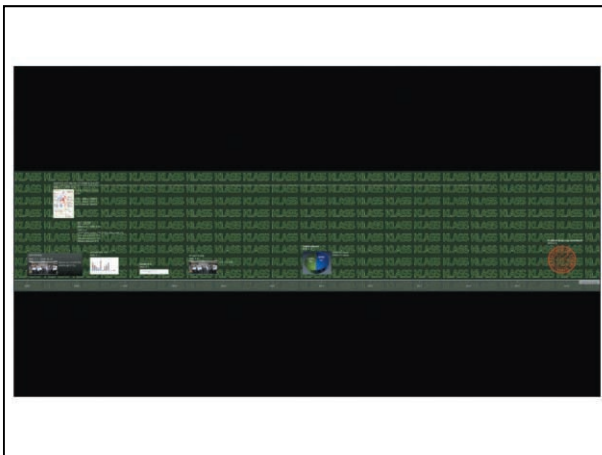
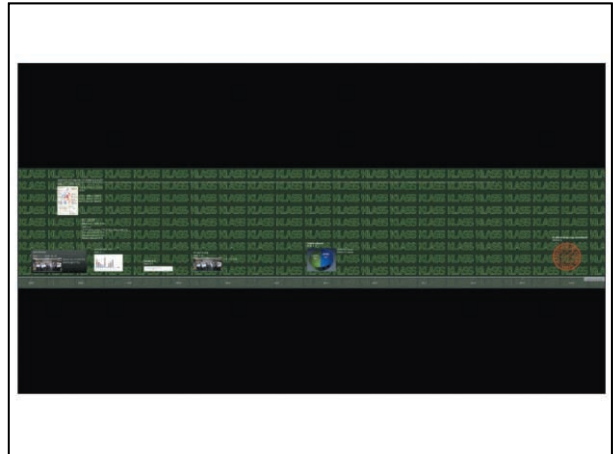
KLASS

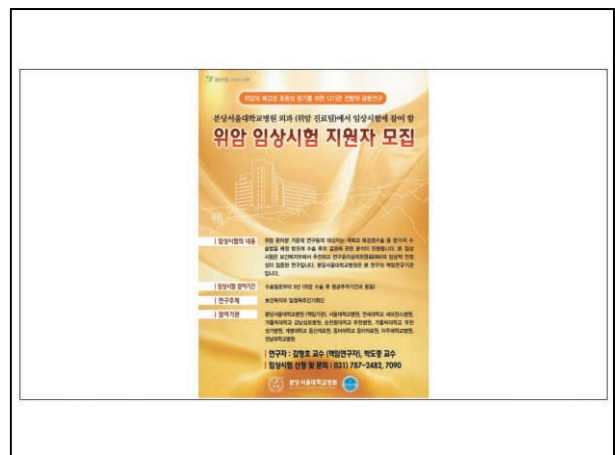
Phase II Morbidity & Mortality

Parameter	LADG (n=179)		ODG (n=163)		p-value
	n	%	n	%	
Early complication	17	10.49	24	14.72	0.137
Re-operation	3	1.68	3	1.84	I
Late complication	1	0.56	2	1.68	I
Mortality	2 [#]	1.12	0	0	0.497

[#] Cause 1st case - hepatitis B, pulmonary, renal, hepatic, MOF
 2nd case - LC(child B), hepatic failure, CRF, acute exacerbation

Kim HH & KLASS Ann Surg. 2010;251:417-420





<p>The Impact of Comorbidity on Surgical Outcomes in Laparoscopy-Assisted Distal Gastrectomy: A Retrospective Analysis of Multicenter Results</p> <p><i>Heek-Joon Lee, MD, PhD, Eun-Sung Song, MD, Heek-Joon Lee, MD, PhD, Sang-Uk Cho, MD, PhD, Woo-Jin Hong, MD, PhD, and Gyo-Sook Cho, MD, PhD</i></p>	<p>Ann Surg 2008;246:793 (IF: 8.46)</p>
<p>Risk Factors Associated with Complication Following Laparoscopy-Assisted Gastrectomy for Gastric Cancer: A Large-Scale Korean Multicenter Study</p> <p><i>Min-Chan Kim, MD, Won-Ki Kim, MD, Hyung-Ho Kim, MD, Seung-Wan Kim, MD, Seung-Yoon Kim, MD, Kyo-Young Song, MD, Heek-Joon Lee, MD, Gyo-Sook Cho, MD, Sang-Uk Cho, MD, Woo-Jin Hong, MD, and Korean Laparoscopic Gastrointestinal Surgery Study (KLASS) Group</i></p>	<p>Ann Surg Oncol 2008;15:2692 (IF: 3.90)</p>
<p>Is Gastrectomy Mandatory for All Residual or Recurrent Gastric Cancer Following Endoscopic Resection? A Large-Scale Korean Multi-Center Study</p> <p><i>Heek-Joon Lee, MD, PhD, Eun-Sung Song, MD, Heek-Joon Lee, MD, PhD, Sang-Uk Cho, MD, PhD, Woo-Jin Hong, MD, PhD, and Korean Laparoscopic Gastrointestinal Surgery Study (KLASS) Group</i></p>	<p>J Surg Oncol 2008;98:6 (IF: 2.48)</p>
<p>The impact of a high body mass index on laparoscopy assisted gastrectomy for gastric cancer</p> <p><i>Heek-Joon Lee, Hyung-Ho Kim, Min-Chan Kim, Seung-Yoon Kim, Won-Ki Kim, Kyo-Young Song, Gyo-Sook Cho, Sang-Uk Cho, Woo-Jin Hong, and Seung-Wan Kim - Korean Laparoscopic Gastrointestinal Surgery Study (KLASS) Group</i></p>	<p>Surg Endosc 2009 Apr 3 [Epub ahead of print] (IF: 3.23)</p>

<p>Laparoscopy-assisted total gastrectomy for gastric cancer: A multicenter retrospective analysis</p> <p><i>Gyo-Sook Cho, MD, PhD, Gyo-Sook Cho, MD, PhD, Heek-Joon Lee, MD, PhD, Seung-Yoon Kim, MD, PhD, Eun-Sung Song, MD, PhD, Sang-Uk Cho, MD, PhD</i></p>	<p>Surgery 2009;146(2) :469-74 (IF: 3.38)</p>
<p>Multicentre study of the safety of laparoscopic subtotal gastrectomy for gastric cancer in the elderly</p> <p><i>G. S. Choi, W. Kim, H. H. Kim, S. W. Ryu, M. C. Kim, and S. Y. Ryu</i></p>	<p>Br J Surg 2009;12 :1437-42 (IF: 4.92)</p>
<p>Recurrence Following Laparoscopy-Assisted Gastrectomy for Gastric Cancer: A Multicenter Retrospective Analysis of 1,417 Patients</p> <p><i>Jeevan Singh, MD, Heek-Joon Lee, MD, Gyo-Sook Cho, MD, Sang-Uk Cho, MD, Min-Chan Kim, MD, Seung-Wan Kim, MD, Won-Ki Kim, MD, Kyo-Young Song, MD, Heek-Joon Lee, MD, Woo-Jin Hong, MD, and Korean Laparoscopic Gastrointestinal Surgery Study (KLASS) Group</i></p>	<p>Ann Surg Oncol 2010;12 (IF: 3.90)</p>
<p>Morbidity and Mortality of Laparoscopic Gastrectomy Versus Open Gastrectomy for Gastric Cancer: An Interim Report—A Phase III Multicenter, Prospective, Randomized Trial (KLASS Trial)</p> <p><i>Heek-Joon Lee, MD, PhD, Eun-Sung Song, MD, PhD, Gyo-Sook Cho, MD, PhD, Heek-Joon Lee, MD, PhD, Sang-Uk Cho, MD, PhD, Woo-Jin Hong, MD, PhD, and Korean Laparoscopic Gastrointestinal Surgery Study (KLASS) Group</i></p>	<p>Ann Surg 2010;251:417-420 (IF: 8.46)</p>

KLASS

KLASS trial

- No. of Case : 700 patients per group (total 1,400 patients)
- Criteria for patients enrollment
 - ✓ T1N0-1 gastric adenocarcinoma
- Criteria for participating surgeons & institutes
 - Institute : more than 80 cases / 1 year
 - Surgeon : LADG > 50cases, ODG > 50cases
- Quality control for Surgery
 - ✓ Site-visit, Video presentation without edition

KLASS

Phase III Comparing with ODG

Main Study Topics

- ✓ Primary end point
 - 5 year overall survival
- ✓ Secondary end point
 - diagnostic accuracy of EUS and CT
 - morbidity and mortality
 - quality of life
 - inflammatory response and immune function
 - cost effectiveness

KLASS

For Better Study

- Review of Unedited Video : Operation Standardization
- Establishment of Surgeon Eligibility Criteria
- Expansion and Exclusion of the Participating Surgeon
- Regular investigator meeting (On & Off-line)
- Reciprocal site-visit Audit for Quality Control

KLASS

Surgeon's Eligibility Criteria

- Personal Experience
 - Over 50 gastrectomies by open & laparoscopy, each
- Hospital Volume
 - Over 80 gastrectomies by annual number

KLASS

Participants

19 surgeons from 16 institutes

- 서울의대 분당서울대병원 : 김형준 (PI), 박도중
- 아주의대 : 한상욱
- 동아대의대 : 김민찬
- 가톨릭대의대 여의도성모병원 : 김욱
- 연세의대 신촌세브란스병원 : 황우진
- 순천향대의대 부천병원 : 조규석
- 서울의대 서울대병원 : 양한광, 이혁준
- 계명대의대 : 류승원
- 전남의대 : 류성업
- 전북대의대 : 김찬영
- 충남대의대 : 이상일
- 이화대의대 목동병원 : 이주호
- 가톨릭대의대 성빈센트병원 : 진형민
- 울산대병원 김규철
- 성균관대의대 삼성서울병원 : 손태선
- 연세의대 강남세브란스병원 : 최승호

연구원 편성표

50명

The chart shows a hierarchical structure starting with a top-level group of 50 researchers, divided into five main branches. Each branch further subdivides into specific roles and departments, such as '연구책임자' (Research Lead), '연구비서' (Research Secretary), and '연구원' (Researcher), with associated counts for each.

연구비

매년 80,000,000원을 정부출연금으로 지원

항목	제1세부	제2세부	제3세부	제4세부	제5세부	합계
인건비	17,600	8,800	8,800	8,800	8,800	52,800
기타	14,400	3,200	3,200	3,200	3,200	27,200
연구사업비 총액	32,000	12,000	12,000	12,000	12,000	80,000

The screenshot shows a search result for 'gastric cancer and Korea' on ClinicalTrials.gov. It lists several ongoing trials, with the first one highlighted: 'Only One phase III surgical trial on gastric cancer'. The table includes trial IDs, titles, and brief descriptions.

Sample Size

- 유의수준 $\alpha=0.05$, 제2종 과오 $\beta=0.20$, 검정력 (power) = 80%
- $n1(ODG) = n2 (LADG)$
- 기존 연구결과를 바탕으로 개복수술인 경우 5YSR 90% ($p1=0.9$)라 추정되며, 복강경 수술 군인 경우도 마찬가지로 가정
- 두 군의 차이가 5% 이내에서는 차이가 존재하지 않는다는 것을 판단하기 위하여 non-inferiority test를 실시
- Log-rank test
- $H0: p1-p2 = 0.05$ vs $H1 p1-p2 > 0.05$

등록기간 2.5년, 탈락율 10%로 계산

Sample Size

환자등록기간의 연장과 탈락율의 증가를 고려한 대상자수
등록기간과 추적관찰기간을 변화시켰을 때 대상자수의 변화 양상

등록 기간	추적 관찰 기간	대상자수	연락률	탈락률	대상자수	연락률	탈락률
2.5	6	433	0.10	700	4.5	1	433
		0.15	748	0.15	740		
		0.20	790	0.20	790		
		0.25	845	0.25	845		
		0.30	905	0.30	905		
3.5	5	474	0.10	750	5	1	474
		0.15	780	0.15	780		
		0.20	840	0.20	770		
		0.25	900	0.25	820		
		0.30	960	0.30	880		
4	5	490	0.10	720	5.5	5	598
		0.15	765	0.15	790		
		0.20	810	0.20	750		
		0.25	865	0.25	800		
		0.30	910	0.30	855		

등록 기간 4.5년, 탈락율 10%로 계산

Data Monitoring

1. Independent Audit를 구성하여 2차년도부터 정기적으로 Site Visiting 실시
 2. Operation Quality의 유지 : 수술소견을 사진으로 web-hard에 게시

Surgeon's Qualification

- 위암 수술 경력
 - 위암 수술 hospital volume: 80개/year
 - 개인의 위암 개복 위절제술 total experience: 50개 이상 시행
 - 개인의 위암 목강경 위절제술 total experience: 50개 이상 시행
- Live surgery qualification
 - : 2인이 직접 관람 수술자의 술기뿐만 아니라 수술 장비, 보조 술자의 참여도, 각 병원의 지원 정도 등을 판단 기준으로 함.
- Raw video qualification
 - : steering committee 4인 이상 찬성

Name	
Department	
Specialty	
Education	1. Hospital (Year) 2. Undergraduate School of Medicine (Year) 3. Residency (Year)
Qualification	A. Live Surgery Ability B. Laparoscopic Surgery
Examination	1. Written 2. Practical
Review	1. Undergraduate 2. Postgraduate (Residency)
Approval	1. Approval (Date) 2. Approval (Date)
Signature	
Stamp	

Audit Check List

1. 위암 수술 시술 전에는...
 2. 위암 수술 시술 후에는...

체계적인 CRF 완성

위암의 특장점 수술의 표준화 평가를 위한
 다기관 현황적 무작위 공동연구

임상 결과 기록지

위암 수술	위암 수술
위암 수술	위암 수술

2014년도 임종학술연구사업(위암) 연구비 지원금 신청서

Critical Pathway 적용

진단 Protocol 확립

Endoscopy Report Form

1. Endoscopy Indication

2. Endoscopy Procedure

3. Endoscopy Findings

EUS Report Form

1. EUS Indication

2. EUS Procedure

3. EUS Findings

CT Report Form

1. CT Indication

2. CT Procedure

3. CT Findings

독창적인 QOL module 제작

주관인생척도, 건강지각척도, 상처관련증상척도

주관인생척도 (QLQ-C30) 항목:

1. 일상생활의 즐거움	1-1	1-2
2. 신체적 기능	2-1	2-2
3. 역할 수행 능력	3-1	3-2
4. 신체적 통증	4-1	4-2
5. 식욕	5-1	5-2
6. 소화	6-1	6-2
7. 배변	7-1	7-2
8. 피로	8-1	8-2
9. 사회적 기능	9-1	9-2
10. 정서적 기능	10-1	10-2
11. 인지 기능	11-1	11-2
12. 기억력	12-1	12-2
13. 의사소통	13-1	13-2
14. 신체적 독립성	14-1	14-2
15. 사회적 독립성	15-1	15-2
16. 정서적 독립성	16-1	16-2
17. 인지적 독립성	17-1	17-2
18. 신체적 독립성	18-1	18-2
19. 사회적 독립성	19-1	19-2
20. 정서적 독립성	20-1	20-2
21. 인지적 독립성	21-1	21-2

건강지각척도 (SAS) 항목:

1. 건강지각	1-1	1-2
2. 통증	2-1	2-2
3. 소화	3-1	3-2
4. 배변	4-1	4-2
5. 피로	5-1	5-2
6. 식욕	6-1	6-2
7. 사회적 기능	7-1	7-2
8. 정서적 기능	8-1	8-2
9. 인지 기능	9-1	9-2
10. 기억력	10-1	10-2
11. 의사소통	11-1	11-2
12. 신체적 독립성	12-1	12-2
13. 사회적 독립성	13-1	13-2
14. 정서적 독립성	14-1	14-2
15. 인지적 독립성	15-1	15-2

상처관련증상척도 (W-TOX) 항목:

1. 통증	1-1	1-2
2. 소화	2-1	2-2
3. 배변	3-1	3-2
4. 피로	4-1	4-2
5. 식욕	5-1	5-2
6. 사회적 기능	6-1	6-2
7. 정서적 기능	7-1	7-2
8. 인지 기능	8-1	8-2
9. 기억력	9-1	9-2
10. 의사소통	10-1	10-2
11. 신체적 독립성	11-1	11-2
12. 사회적 독립성	12-1	12-2
13. 정서적 독립성	13-1	13-2
14. 인지적 독립성	14-1	14-2

2007 대한위암학회 추계학술대회

위암의 복강경 수술의 효용성 평가를 위한 삶의 질에 관한 설문지의 신뢰도와 타당도

- Korean Laparoscopic Gastrointestinal Surgery Study Group (KLASS Trial) -

조규석, 김민창기, 김 욱자, 김형호, 류성열, 류승원, 송교영, 이혜준, 한성욱, 형우진, 박준호

순천향대학교 의과대학 외과학교실, 서울대학교 의과대학 외과학교실, 가톨릭대학교 의과대학 외과학교실, 경희대학교 의과대학 외과학교실, 건국대학교 의과대학 외과학교실, 연세대학교 의과대학 외과학교실, 아주대학교 의과대학 외과학교실, 순천향대학교 의과대학 정신과학교실

결론

- ◆ QLQ-C30, ST022, 주관인생, 치료 만족도, 건강지각, 상처 관련 증상, 흉터 관련 척도의 신뢰도와 타당도는 만족할만한 수준이었다.
- ◆ QLQ-C30 척도와 ST022 척도의 요인타당도를 보면 원칙도의 요인구조와 일치되지 않는 이유는 문화적 차이에 의해서 나타났을 가능성이 있으며, 한국판 C-30 척도와 ST022 척도가 가지는 고유 요인을 탐색할 필요가 있다.

암정복 다기관 연구 발표

2005 대한위암연구학회, 2005 Japan-Korea Laparoscopic Gastrectomy Joint Seminar, 2005 APCC, 2006 일본위암학회

암정복 다기관 연구 발표 프로그램

2005 대한위암연구학회: 위암의 진단, 치료, 예방, 예후, 재활, 그리고 삶의 질을 위한 다기관 연구 발표

2005 Japan-Korea Laparoscopic Gastrectomy Joint Seminar: 위암의 진단, 치료, 예방, 예후, 재활, 그리고 삶의 질을 위한 다기관 연구 발표

2005 APCC: 위암의 진단, 치료, 예방, 예후, 재활, 그리고 삶의 질을 위한 다기관 연구 발표

2006 일본위암학회: 위암의 진단, 치료, 예방, 예후, 재활, 그리고 삶의 질을 위한 다기관 연구 발표

암정복 다기관 연구 발표 (집담회 개최)

37th Conference of Korean Laparoscopic Surgery Study Group

Introduction of KLASS Trial and Status Report

Program

8:30-9:00 Registration

9:00-9:30 Session 1: Introduction of KLASS Trial and Status Report

9:30-10:00 Session 2: Comparison of Laparoscopic and Open Gastrectomy for Gastric Cancer

10:00-10:30 Session 3: Quality of Life in Gastric Cancer Patients

10:30-11:00 Session 4: Prognostic Factors in Gastric Cancer

11:00-11:30 Session 5: Adjuvant Therapy in Gastric Cancer

11:30-12:00 Session 6: Gastric Cancer in the Elderly

12:00-12:30 Lunch

12:30-1:00 Session 7: Gastric Cancer in the Young

1:00-1:30 Session 8: Gastric Cancer in the Asian

1:30-2:00 Session 9: Gastric Cancer in the African

2:00-2:30 Session 10: Gastric Cancer in the Latin American

2:30-3:00 Session 11: Gastric Cancer in the Middle East

3:00-3:30 Session 12: Gastric Cancer in the Oceania

3:30-4:00 Session 13: Gastric Cancer in the Europe

4:00-4:30 Session 14: Gastric Cancer in the North America

4:30-5:00 Session 15: Gastric Cancer in the South America

5:00-5:30 Session 16: Gastric Cancer in the Africa

5:30-6:00 Session 17: Gastric Cancer in the Asia

6:00-6:30 Session 18: Gastric Cancer in the Oceania

6:30-7:00 Session 19: Gastric Cancer in the Europe

7:00-7:30 Session 20: Gastric Cancer in the North America

7:30-8:00 Session 21: Gastric Cancer in the South America

8:00-8:30 Session 22: Gastric Cancer in the Africa

8:30-9:00 Session 23: Gastric Cancer in the Asia

9:00-9:30 Session 24: Gastric Cancer in the Oceania

9:30-10:00 Session 25: Gastric Cancer in the Europe

10:00-10:30 Session 26: Gastric Cancer in the North America

10:30-11:00 Session 27: Gastric Cancer in the South America

11:00-11:30 Session 28: Gastric Cancer in the Africa

11:30-12:00 Session 29: Gastric Cancer in the Asia

12:00-12:30 Session 30: Gastric Cancer in the Oceania

12:30-1:00 Session 31: Gastric Cancer in the Europe

1:00-1:30 Session 32: Gastric Cancer in the North America

1:30-2:00 Session 33: Gastric Cancer in the South America

2:00-2:30 Session 34: Gastric Cancer in the Africa

2:30-3:00 Session 35: Gastric Cancer in the Asia

3:00-3:30 Session 36: Gastric Cancer in the Oceania

3:30-4:00 Session 37: Gastric Cancer in the Europe

4:00-4:30 Session 38: Gastric Cancer in the North America

4:30-5:00 Session 39: Gastric Cancer in the South America

5:00-5:30 Session 40: Gastric Cancer in the Africa

5:30-6:00 Session 41: Gastric Cancer in the Asia

6:00-6:30 Session 42: Gastric Cancer in the Oceania

6:30-7:00 Session 43: Gastric Cancer in the Europe

7:00-7:30 Session 44: Gastric Cancer in the North America

7:30-8:00 Session 45: Gastric Cancer in the South America

8:00-8:30 Session 46: Gastric Cancer in the Africa

8:30-9:00 Session 47: Gastric Cancer in the Asia

9:00-9:30 Session 48: Gastric Cancer in the Oceania

9:30-10:00 Session 49: Gastric Cancer in the Europe

10:00-10:30 Session 50: Gastric Cancer in the North America

10:30-11:00 Session 51: Gastric Cancer in the South America

11:00-11:30 Session 52: Gastric Cancer in the Africa

11:30-12:00 Session 53: Gastric Cancer in the Asia

12:00-12:30 Session 54: Gastric Cancer in the Oceania

12:30-1:00 Session 55: Gastric Cancer in the Europe

1:00-1:30 Session 56: Gastric Cancer in the North America

1:30-2:00 Session 57: Gastric Cancer in the South America

2:00-2:30 Session 58: Gastric Cancer in the Africa

2:30-3:00 Session 59: Gastric Cancer in the Asia

3:00-3:30 Session 60: Gastric Cancer in the Oceania

암정복 다기관 연구 발표

Japan-Korea Laparoscopic Gastric Surgery Joint Seminar

February 18, Saturday, 2005

Tokyo, Oda, Japan

9:30 Opening Remarks

9:30-10:00 Session 1: Comparison of Laparoscopic versus Open Gastrectomy for Gastric Cancer: a phase II trial

10:00-10:30 Session 2: Quality of Life in Gastric Cancer Patients

10:30-11:00 Session 3: Prognostic Factors in Gastric Cancer

11:00-11:30 Session 4: Adjuvant Therapy in Gastric Cancer

11:30-12:00 Session 5: Gastric Cancer in the Elderly

12:00-12:30 Lunch

12:30-1:00 Session 6: Gastric Cancer in the Young

1:00-1:30 Session 7: Gastric Cancer in the Asian

1:30-2:00 Session 8: Gastric Cancer in the African

2:00-2:30 Session 9: Gastric Cancer in the Latin American

2:30-3:00 Session 10: Gastric Cancer in the Middle East

3:00-3:30 Session 11: Gastric Cancer in the Oceania

3:30-4:00 Session 12: Gastric Cancer in the Europe

4:00-4:30 Session 13: Gastric Cancer in the North America

4:30-5:00 Session 14: Gastric Cancer in the South America

5:00-5:30 Session 15: Gastric Cancer in the Africa

5:30-6:00 Session 16: Gastric Cancer in the Asia

6:00-6:30 Session 17: Gastric Cancer in the Oceania

6:30-7:00 Session 18: Gastric Cancer in the Europe

7:00-7:30 Session 19: Gastric Cancer in the North America

7:30-8:00 Session 20: Gastric Cancer in the South America

8:00-8:30 Session 21: Gastric Cancer in the Africa

8:30-9:00 Session 22: Gastric Cancer in the Asia

9:00-9:30 Session 23: Gastric Cancer in the Oceania

9:30-10:00 Session 24: Gastric Cancer in the Europe

10:00-10:30 Session 25: Gastric Cancer in the North America

10:30-11:00 Session 26: Gastric Cancer in the South America

11:00-11:30 Session 27: Gastric Cancer in the Africa

11:30-12:00 Session 28: Gastric Cancer in the Asia

12:00-12:30 Session 29: Gastric Cancer in the Oceania

12:30-1:00 Session 30: Gastric Cancer in the Europe

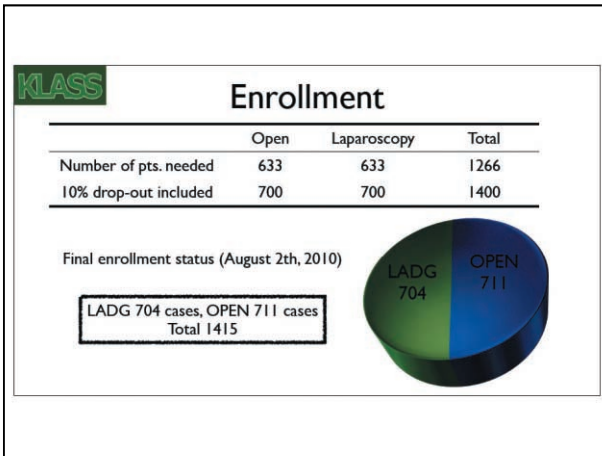
1:00-1:30 Session 31: Gastric Cancer in the North America

1:30-2:00 Session 32: Gastric Cancer in the South America

2:00-2:30 Session 33: Gastric Cancer in the Africa

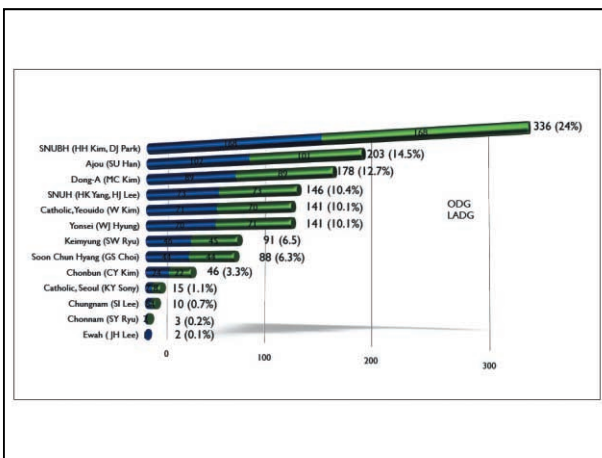
2:30-3:00 Session 34: Gastric Cancer in the Asia

3:00-3:30 Session 35: Gastric Cancer in the Oceania



2010-07-09기준	배정현황			CRF 도착현황		
	개복	복강경	TOTAL	개복	복강경	TOTAL
종아대	89	89	178	87	84	171
연세대	70	71	141	69	70	139
부원순천향대	44	44	88	42	40	82
서울대-연건	73	73	146	73	72	145
서울대-분당	168	167	335	158	157	315
강남성모	7	8	15	2	4	6
계명대	46	45	91	42	45	87
부원성가	71	70	141	70	70	140
아주대	102	101	203	102	101	203
전남대	2	1	3	0	0	0
중앙대	6	4	10	0	0	0
전북대	24	23	47	24	23	47
외대목동	1	1	2	1	1	2
합계	703	697	1400	670	667	1337

동의철회 vs. Non-compliance



KLASS Surgical Quality Control

KLASS trial versus Previous study

	KLASS	Dutch	SWOG 9008	JCOG 9501	JCOG 9502
No of Pt enrolled / Hospital	108.8	13.5	2	21.8	6.2
No of Pt enrolled / Hospital/Yr	24	3.4	0.3	3.6	0.8

KLASS 7th TNM stage (n=1415)

Stages	LAG (n=704)	OG (n=711)	p
IA	529 (75.5%)	483 (71.6%)	0.431
IB	83 (11.8%)	79 (11.7%)	
IIA	36 (5.1%)	46 (6.8%)	
IIB	22 (3.1%)	34 (5.0%)	
IIIA	19 (2.7%)	19 (2.8%)	
IIIB	7 (1.0%)	5 (0.7%)	
IIIC	4 (0.6%)	7 (1.0%)	
IV	1 (0.1%)	2 (0.3%)	

KLASS, Unpublished data

KLASS Morbidity & Mortality

	LAG (n=704)	OG (n=711)	p
Morbidity	95 (13.4%)	136 (19.8%)	0.001
Mortality	3 (0.4%)	2 (0.3%)	0.681

KLASS, Unpublished data

Conclusions

- Same long-term oncologic outcomes , retrospectively
- Selection bias and not enough patient's numbers of advanced stage.
- Needs RCT for advanced gastric cancer
- Less morbidity and same surgical mortality, prospectively
- We will report the long-term outcomes in 2015.

KLASS 01 Study Long-Term Results

1 1 3 4

Collateral Studies in RCT of Gastric Cancer Surgery Dutch Trial (D1 vs. D2, n=996, 1989-1993)

Topic	First	Corresponding	Journal	IF (2008)
5-yr survival	Bonenkamp JJ	van de Velde CJH	NEJM, 1999	74.6
M & M	Bonenkamp JJ	van de Velde CJH	Lancet, 1996	28.4
10-yr survival	Hartgrink HH	Hartgrink HH	JCO, 2004	17.2
Prediction of DFS	Peeters KCM	van de Velde CJH	Cancer, 2005	5.3
Risk factor for Cx	Sasako M	Sasako M	Br J Surg, 1997	4.9
Wash. cytology	Bonenkamp JJ	van de Velde CJH	Br J Surg, 1996	4.9
Maruyama index	Peeters KCM	Hundahl SA, van de Velde CJH	World J Surg, 2005	2.6
Maruyama index	Hundahl SA	Hundahl SA	Gastric cancer, 2007	
Quality control	Sasako M	Sasako M	JCO, 1992	1.4
15-yr result	Songun I	Van de Velde CJH	Lancet Oncol, 2010	

Collateral Studies in RCT of Gastric Cancer Surgery Taiwan trial (D1 vs. D3, n=221, single center)

Topic	First	Corresponding	Journal	IF (2008)
5-yr survival	Wu CW	Wu CW	Lancet Oncol, 2006	13.5
M & M	Wu CW	Wu CW	Br J Surg, 2004	4.9
QOL	Wu CW	Wu CW	Br J Cancer, 2005	4.8
Risk factor for Cx	Wu CW	Wu CW	World J Surg, 2006	2.6
Stage migration	Wu CW	Wu CW	EJSO, 2005	2.5

Collateral Studies in RCT of Gastric Cancer Surgery JCOG trial (D2 vs. D2+PA, n=523)

Topic	First	Corresponding	Journal	IF (2008)
5-yr survival	Sasako M	Sasako M	NEJM, 2008	74.6
M & M	Sano T	Sano T	JCO, 2004	17.2
Risk factor for Cx	Kodera Y	Kodera Y	Br J Surg, 2005	4.9
Stage migration	Yoshikawa T	Yoshikawa T	Br J Surg, 2006	4.9
Obesity	Tsujinaka T	Tsujinaka T	ASO, 2007	3.9
Risk factor for PA-1N meta	Nomura E	Nomura E	JCO, 2007	1.4

COST trial (Open vs. Lapa for Colon cancer, n=872, 1994-2001)

Topic	First	Corresponding	Journal	IF (2008)
3-yr survival	COST	Nelson H	NEJM, 2004	74.6
QOL	Weeks JC	Weeks JC	JAMA, 2002	31.7
8-yr survival	Fleshman J	Nelson H	Ann Surg, 2007	8.5
Surgeon Volume	Larson DW	Larson DW	Ann Surg, 2008	8.5

Spain trial (Open vs. Lapa for Colon cancer, n=219, single center)

Topic	First	Corresponding	Journal	IF (2008)
5-yr survival	Lacy AM	Lacy AM	Lancet, 2002	28.4
10-yr survival	Lacy AM	Lacy AM	Ann Surg, 2008	8.5
M & M	Lacy AM	Lacy AM	Surg Endosc, 1995	3.2
Port site recur	Lacy AM	Lacy AM	Surg Endosc, 1998	3.2
Acute phase response	Delgado S		DCR, 2001	2.6

COLOR trial (Open vs. Lapa for Colon cancer, n=1248)

Topic	First	Corresponding	Journal	IF (2008)
3-yr DFS	COLOR		Lancet Oncol, 2005	13.5
M & M	COLOR	Bonjer HJ	Lancet Oncol, 2005	13.5
Cost	Janson M	Janson M	Br J Surg, 2004	4.9
Intro (interim)	COLOR	Hazebroek EJ	Surg Endosc, 2002	3.2
Hospital Volume	COLOR	Kuhry E	Surg Endosc, 2005	3.2

- ### Possible Collateral Studies in KLASS
- Extended Survival (10-year)
 - Recurrence pattern
 - Surgeon or hospital volume
 - Tumor marker
 - Elderly
 - Risk factor for Cx.
 - Post-EMR
 - Obesity (BMI)
 - Anastomosis technique & related Cx.
 - Postgastrectomy pancreatitis
 - Familial clustering
 - Standardization of surgery & posop. management (CP)
 - Analysis of post-randomization drop-off patients

예상 연구 성과 (연구논문)

	중요도 (가중치)	1단계 목표	2단계 목표	3단계 목표	누계치 (최종 연구종료시)	최종연구종류 후 3년	총계
SCI	75	10	10	8	28	11	42
Non-SCI	15	8	6	6	20	5	30

