

China Multicenter Study of Sentinel Node Biopsy Substituting Axillary Node Dissection: CBCSG-001 Trial with 5 Years Follow-up

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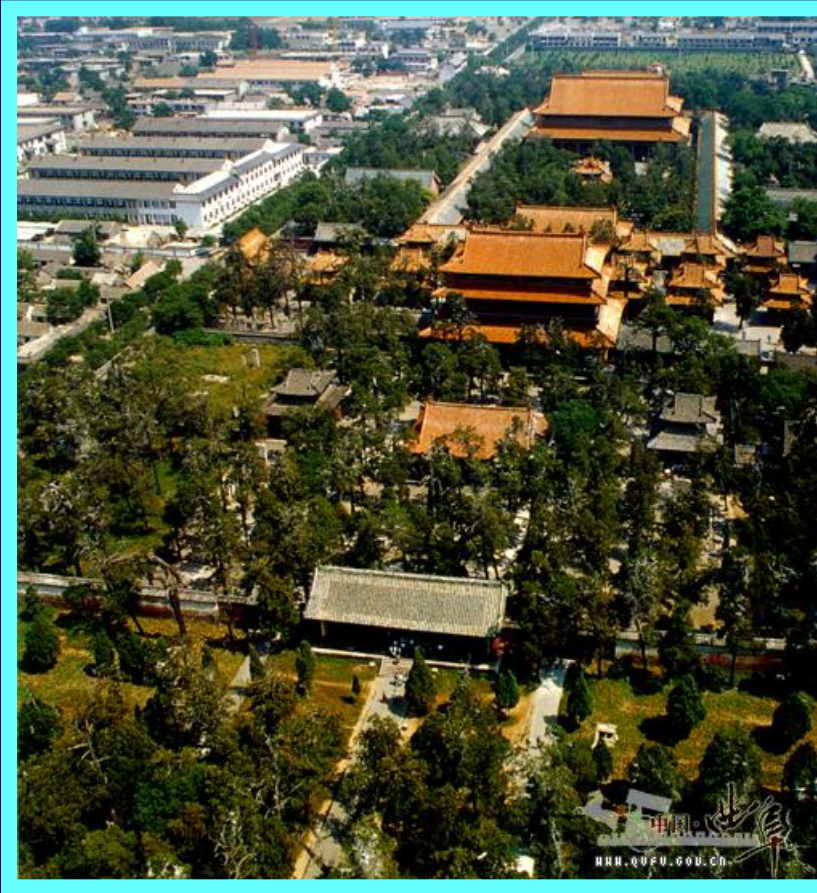
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Shandong: Birth Place of Confucius

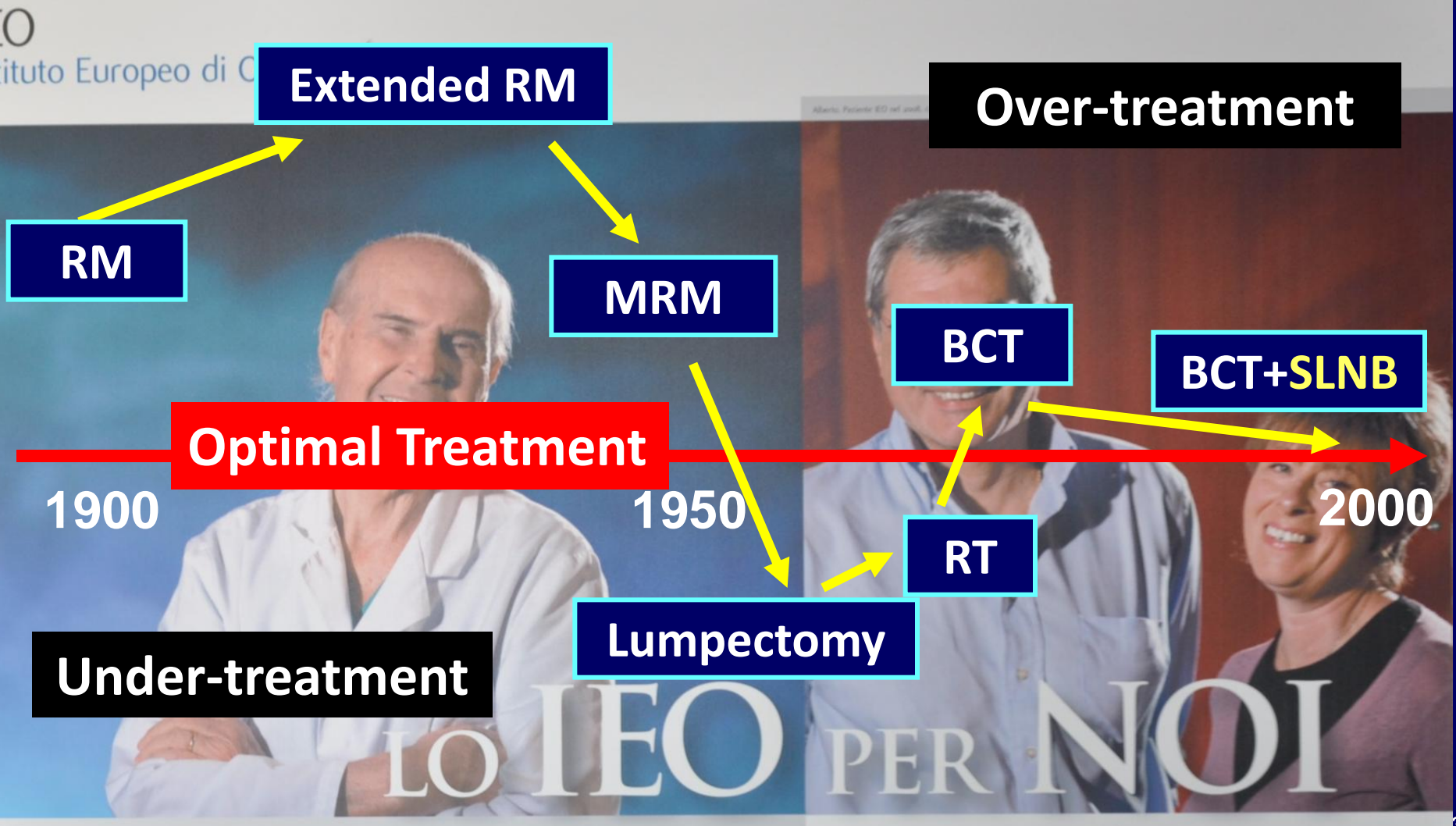


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Optimal Loco-Regional Therapy



Axillary Lymph Node Dissection

■ ALND: Goals

- Staging
- Treatment: Locoregional control & OS improvement
- Guiding adjuvant therapy



■ ALND: complications

- Pain
- Drainage
- Physical capacity ↓
- Paresthesia
- Hydrops
- Infection
- Shoulder-joint motion ↓
- **Lymphedema**

■ ALND: Rationality

- Define adjuvant therapy: Risk → Response + risk
- Treatment: Over-treatment for node negative patients
- Staging: SLNB to substitute ALND

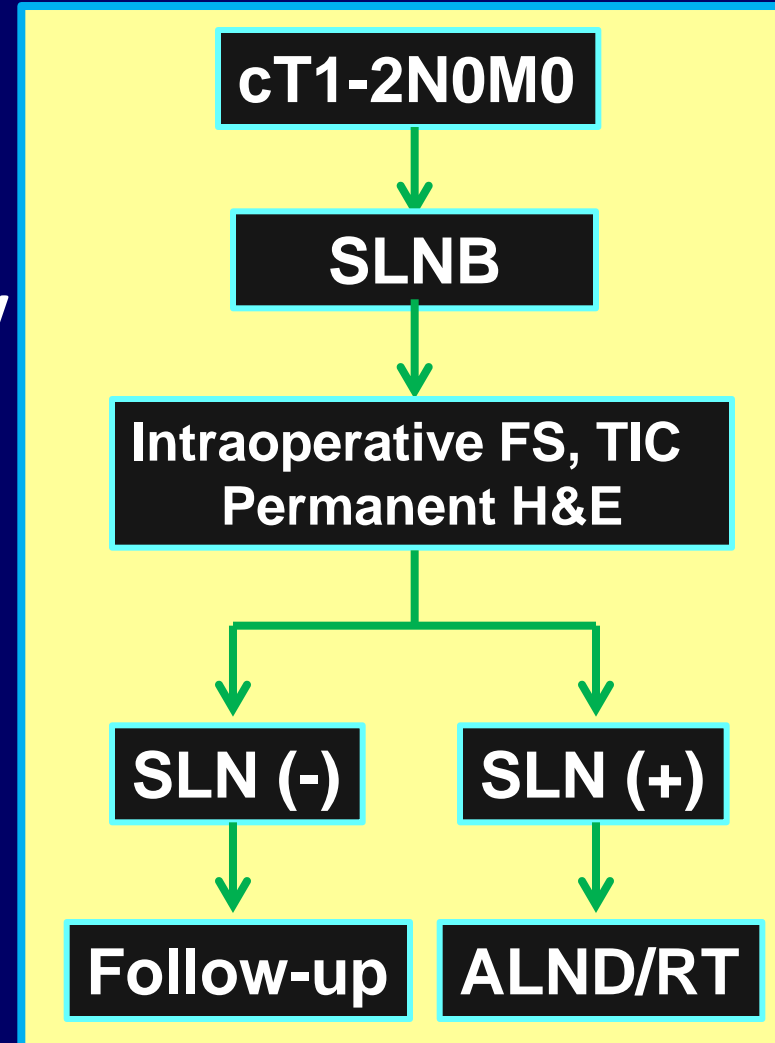
CBCSG-001: Design and Objectives

□ Study design

- Prospective, multicenter, nonrandomized control study
- Preoperative lymphoscintigraphy is mandatory
- Enrollment: 2002.01-2007.06
- Pts no.: 2,000, with about 1,500 SLNB Substituting for ALND

□ Study objectives

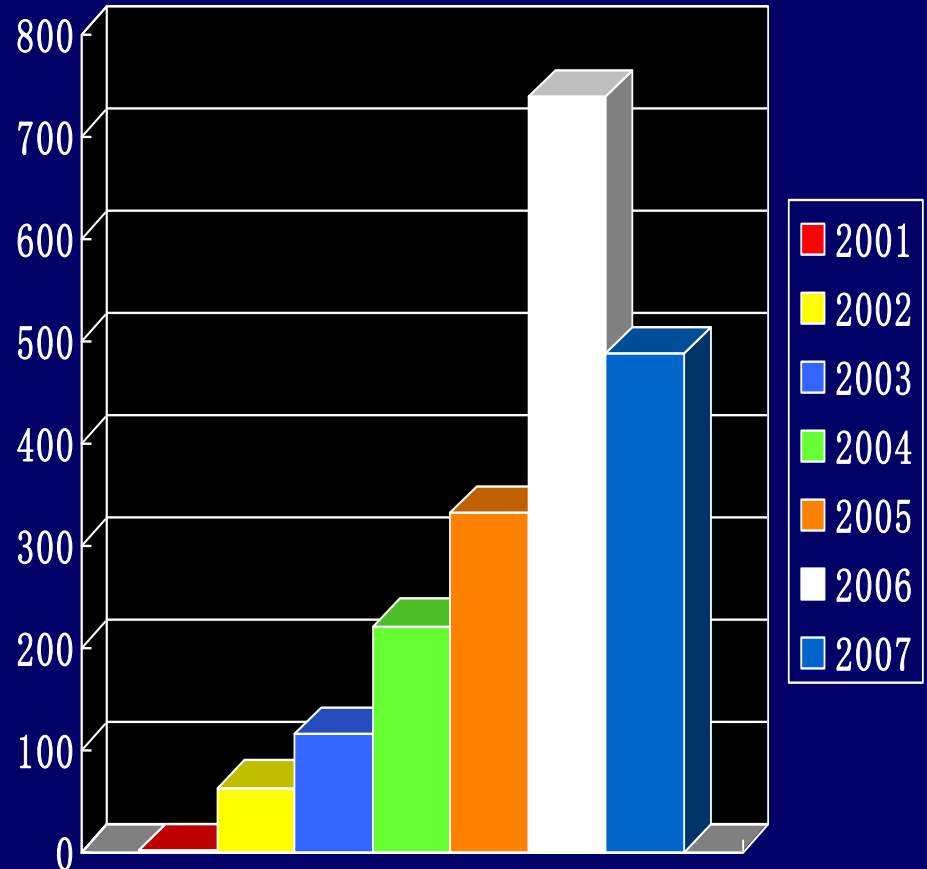
- Primary: 5yrs DFS, Complications
- Secondary: 5yrs OS, SLN intraoperative diagnosis



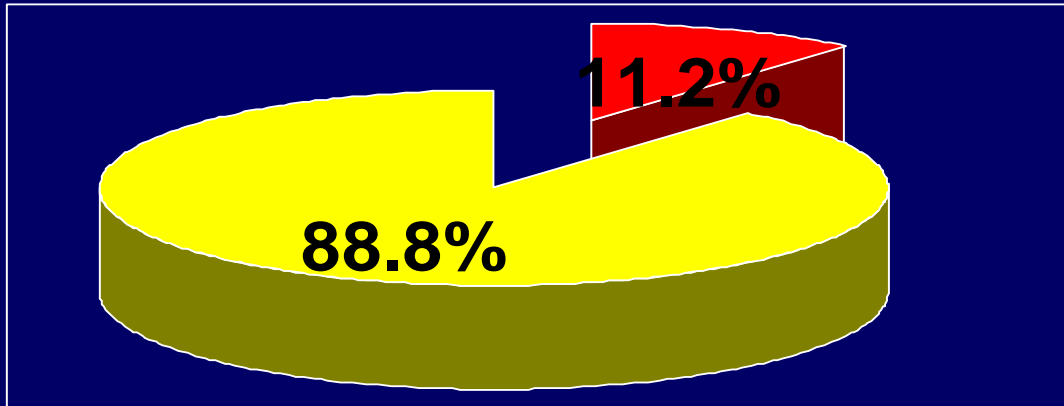
Centers and Pts. Enrollment

Centers

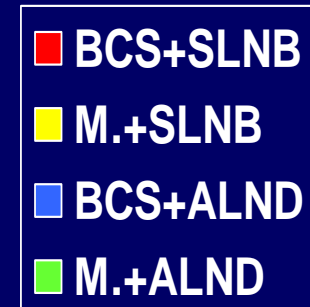
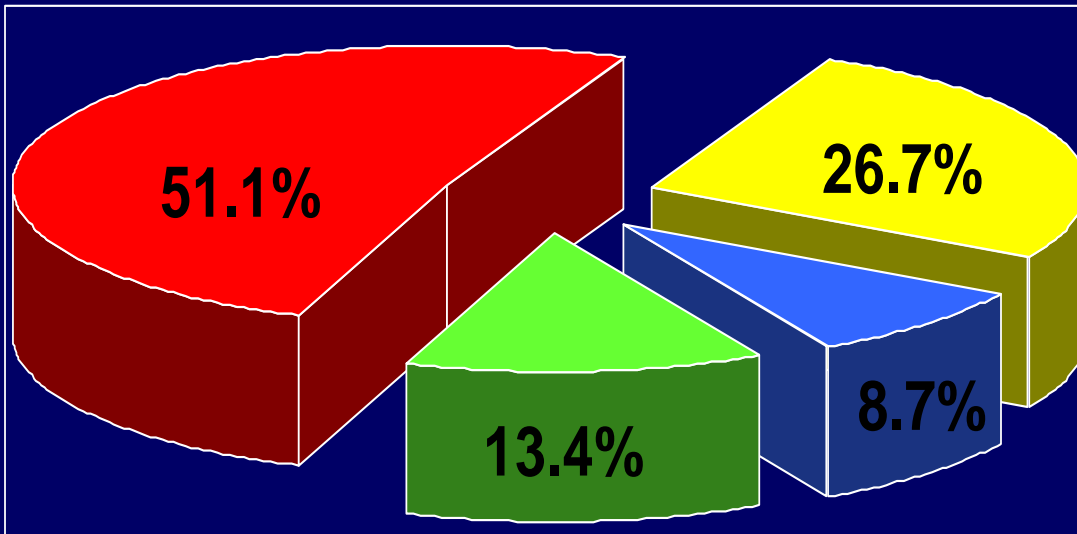
➤ Shandong Cancer H.	550
➤ Beijing Cancer H.	610
➤ 2 nd H. Qingdao U.	270
➤ 2 nd H. Zhongshan U.	227
➤ Yantai Yuhuangding H.	118
➤ Shanghai Cancer H.	83
➤ 307 H. Beijing	50
➤ Xuzhou Central H.	47
➤ Jiangsu people's H.	15
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	1,970



Tracer and Surgical Type



Tracer type



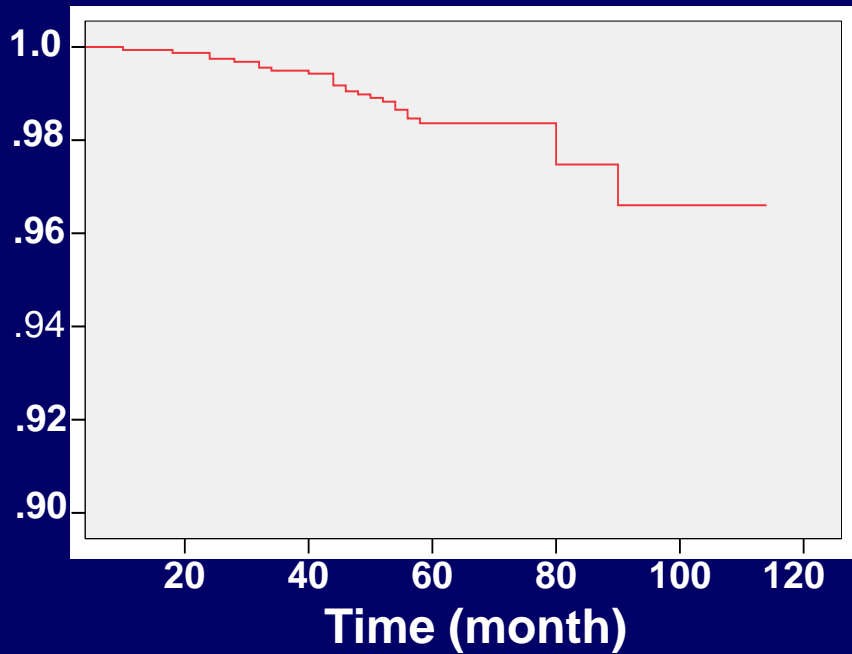
Surgical type

SLN Metastases

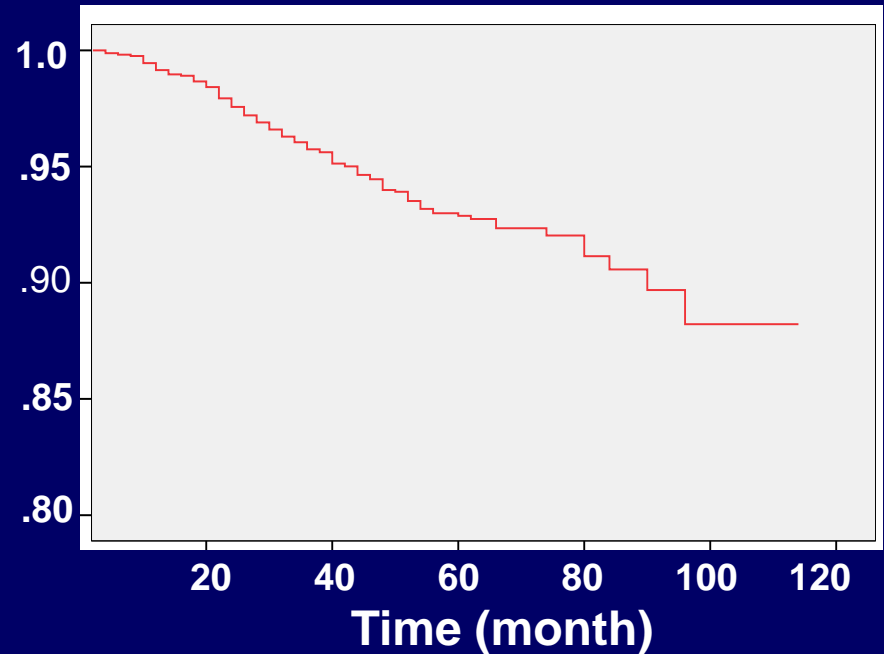
	Case No	SLN + (%)
Primary tumor size	p=0.000	
T≤1cm	180	9.6%
T1~2cm	856	19.9%
T> 2cm	580	32.3%

OS and DFS with SLNB in SLN -ve Pts

5yr OS 98.2%



5yr DFS 94.2%



Regional Relapse with SLNB in SLN -ve Pts

Author	Pts.	Regional Relapse(%)	Median F/U (month)
Imoto	112	4 (3.6)	52
Torrenga	104	1 (1.0)	57
Veronesi	953	3 (0.3)	38
De Kanter	149	4 (2.7)	65
CBCSG-001	1595	9 (0.6)	60

Quality of Life: SLNB vs. ALND

The complications of SLNB were significantly lowered and QOL improved



Quality of Life: SLNB vs. ALND

Lymphedema

Shoulder function

Table 2

Multivariate analysis using logistic regression in patients with lymphedema at 6 months after first surgery.

Variable	β	<i>p</i>	Odds ratio 95% CI
Age (<50, \geq 50 years)	0.471	0.492	0.613 (0.152–2.478)
BMI (<25, \geq 25)	9.321	0.002	9.304 (2.222–38.956)
Type of axillary surgery (SLNB, ALND)	8.514	0.004	7.153 (1.908–26.821)

Table 3

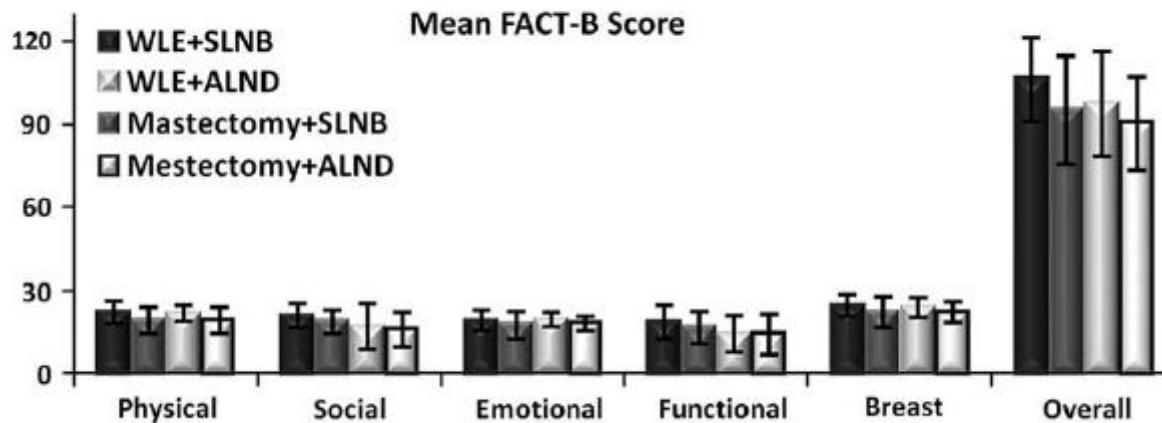
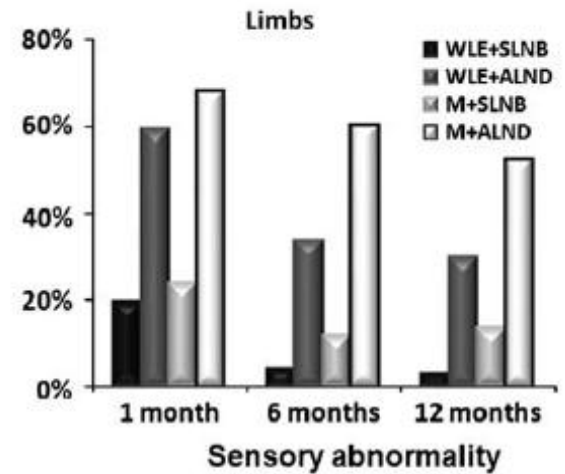
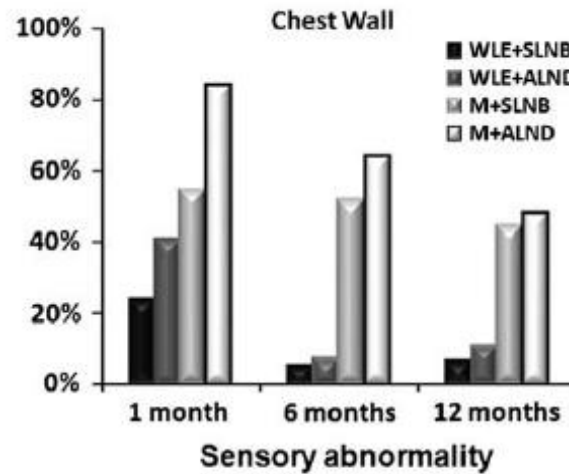
Change in range of movement at one month after surgery.

Movement Restriction (°) ^a	Wide Local Excision		<i>p</i>	Mastectomy		<i>p</i>
	SLNB (<i>n</i> = 72)	ALND (<i>n</i> = 43)		SLNB (<i>n</i> = 68)	ALND (<i>n</i> = 38)	
Flexion	8.9 ± 10.4	20.2 ± 13.7	<0.001	17.7 ± 15.2	35.8 ± 24.2	0.002
Extension	6.4 ± 10.4	20.4 ± 23.4	0.006	9.0 ± 10.8	20.6 ± 20.5	0.013
Adduction	3.4 ± 4.9	10.0 ± 11.6	0.009	6.3 ± 7.7	16.8 ± 20.7	0.022
Abduction	11.0 ± 19.0	40.6 ± 44.9	0.003	21.0 ± 21.1	50.0 ± 44.5	0.005
Internal rotation	4.6 ± 9.0	13.9 ± 21.0	0.038	7.4 ± 10.8	26.8 ± 31.6	0.007
External rotation	2.7 ± 10.4	13.3 ± 18.7	0.010	4.1 ± 6.5	20.2 ± 29.9	0.015

Quality of Life: SLNB vs. ALND

Sensory abnormality

QoL



	1mon	6mon	12mon
D	0.014	0.002	0.002
	0.017	0.001	0.006

CBCSG-001 Conclusions



- Minimally invasive staging for axilla
- SLNB could replace ALND for SLN -ve patients with low axillary recurrence, less complications, and improved quality of life
- SLNB should be the standard of care for clinically axillary negative breast cancer patients

Shandong Cancer Hospital

Thank You

Shandong Breast Center

