

식도영역 자료추출 및 비뚤림위험

연번(Ref ID)	1(5059)																													
1저자(출판연도)	de Groot(2020) (ROBOT trial)																													
연구특성	<ul style="list-style-type: none"> 연구수행국: 네덜란드 연구설계: RCT 연구기관: 단일기관 연구 ROBOT trial 연구수행기간: 2012년 4월~2016년 8월 ROBOT trial NCT01544790; 질환명(세부내용) <ul style="list-style-type: none"> - surgically resectable (cT1-4a, N0-3, M0) cancer of the intrathoracic esophagus 																													
연구대상	<ul style="list-style-type: none"> 선택기준 <ul style="list-style-type: none"> - 18세 이상 80세 이하의 성인 - 식도암 적출가능 환자 환자수 : 109명(중재군=54, 대조군=55명) 																													
중재법	<ul style="list-style-type: none"> 중재명: robot-assisted minimally invasive esophagectomy (RAMIE) 																													
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funding																														
비고																														

* 제 1저자 기준

자료추출 양식(안)_중재평가

연번(Ref ID)	2(9011)																																																																																																												
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Postoperative bleeding	54	2	4	55	2	4	1.00
Readmission intensive care unit, 재입원	54	10	19	55	7	13	0.41
Hospital readmission within 30 days [n (%)]	54	6	12	55	4	7	0.52
Reoperations, 재수술	54	13	24	55	18	33	0.32
In-hospital mortality	54	2	4	55	1	2	0.62
30-Day mortality	54	1	2	55	0	0	0.50
60-Day mortality	54	3	6	55	1	2	0.36
90-Day mortality	54	5	9	55	1	2	0.11
Additional PCA after removal of epidural [n (%)]	54	1	2	55	5	9	0.11
Conversion [n (%)]	54	3	5	55	NA		
Intraoperative complications [n (%)]	54	17	13	55	9	16	0.62

• 결과

연구결과-유효성

변수	RAMIE			OTE			군간 P-value
	N	n	%	N	n	%	
Hospital stay (days—IQ range)	54	14	(11-25)	55	16	(11-27)	0.33
Functional recovery within first 2 weeks [n (%)]	54	38	70	55	28	51	0.04
Quality of life (QLQ-C30)							
Health-related quality of life (discharge)	31	57.9	(49.9-66.1)	33	44.6	(36.7-52.5)	0.02
Health-related quality of life (6 wk) 95% CI.	31	68.7	(61.5-75.9)	33	57.6	(50.6-64.6)	0.03
Physical functioning (discharge)	31	54.5	(45.8-63.3)	33	41.0	(32.4-49.6)	0.03
Physical functioning (6 wk)	31	69.3	(61.6-76.9)	33	58.6	(51.1-66.0)	0.049
수술후 통증 VAS	54	1.86		55	2.62		<0.001
	N	mean	SD	N	mean	SD	
Total Operating time (분)	54	349	56.9	55	296	33.9	<0.001
Total blood loss, mL—IQ range	54	400	258-581	55	568	428-800	<0.001
Lymph nodes number (number—IQ range)	54	27	(17-33)	55	25	(17-31)	0.41

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연구대상	<ul style="list-style-type: none"> • NCT03094351 • 질환명(세부내용) <ul style="list-style-type: none"> - 식도암(esophageal squamous cell carcinoma (ESCC)) • 선택기준 <ul style="list-style-type: none"> - 18 ~ 75세 - European Clinical Oncology Group performance status of 0, 1, or 2, with primarily resectable ESCC [cT1-4a, N0-2, and M0 or M1 (lymph node metastasis confined to the supraclavicular lymph nodes), 7th edition of the American Joint Committee for Cancer staging manual 15] of the intrathoracic esophagus • 환자수 : 181/177 • 연령(median (range)): 65 (43-75)/63 (42-75) 																																																																																								
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Type I (transient injury requiring no therapy)	55	30.4	45	25.4		
Type II (requiring elective surgical procedure)	1	0.6	1	0.6		
Type III (requiring acute surgical intervention)	3	1.7	2	1.1		
Location (Left/right/bilateral)	49 (27.1)/6 (3.3)/4 (2.2)		41 (23.2)/4 (2.3)/3 (1.7)		0.573	
Chylothoraxy	5	2.8	2	1.1	0.449	
Type I (enteric dietary modifications)	4	2.2	1	0.6		
Type II (total parenteral nutrition)	1	0.6	1	0.6		
Type III (interventional or surgical therapy)	0	0	0	0		
Wound infections	3	1.7	1	0.6	0.623	
Intensive care unit stay (d), median (range)	1	0-15	1	0-14	0.990	
Readmission intensive care unit	3	1.7	3	1.7	0.815	
Conversion	7	3.9	6	(3.4)	0.926	

• 결과

연구결과-유효성

변수	RAMIE(181)		MIE (177)		P value
	mean	SD	mean	SD	
Total operation time	203.8	59.4	244.9	61.0	<0.001
Blood loss [median (IQR)]	200	(100-400)	200	(100-500)	0.382
Total Number of LNs[median (IQR)]	23	16-33	23	14-30	0.636
Postoperative hospital stay (d), median (range)	9	6-49	9	6-82	0.311
	n	%	n	%	
In-hospital mortality*	0	0	0	0	
30-d mortality*	0	0	1	0.6	0.633
90-d mortality*	1	0.6	1	0.6	0.909

*생존율로 변경하여 활용

결론

초기 결과는 RAMIE와 MIE가 모두 식도암 수술에 안전하고 실현 가능하다고 보고함. RAMIE는 새로운 보조치료를 받는 환자에서 더 짧은 수술 기간과 더 나은 림프절 절제를 할수 있다는 것을 보고함.

funding

비고

* 제 1저자 기준

비뚤림 위험 평가		
Risk of Bias (RCT인 경우만)		
영역	비뚤림 위험	판단근거(논문인용)
무작위 배정순서 생성	<input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> concealment of allocation was performed using computergenerated random numbers
배정순서 은폐	<input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> concealment of allocation was performed using computergenerated random numbers
참여자, 연구자 눈가림 여부	<input checked="" type="checkbox"/> 높음 <input type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> There was no blinding for the patient and operator due to practical difficulties.
결과 평가자 눈가림 여부	<input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> All outcomes were recorded and prospectively reviewed by the central study coordinator of the trial
불완전한 결과자료	<input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> 사전 중재군 대조군 환자수가 각각 183명, 179명에서 사후 181명, 177명으로 결측치가 결과에 영향을 미치지 않음 The demographic and clinical characteristics of the 2 groups did not differ significantly at baseline
선택적 결과보고	<input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> 프로토콜이 존재하지 않지만 연구방법에서 사전에 정의해놓은 결과들이 연구결과에서 모두 제시되고 있음
기타 비뚤림 위험 (민간연구비 지원)	<input type="checkbox"/> 높음 <input checked="" type="checkbox"/> 낮음 <input type="checkbox"/> 불확실	<ul style="list-style-type: none"> 의료기기 업체의 지원을 받지 않음 This study was funded by the Shanghai Hospital Development Center