



SOCIETÀ POLISPECIALISTICA
ITALIANA GIOVANI CHIRURGI

LA FORMAZIONE DEL GIOVANE CHIRURGO Il futuro siamo noi



Update della letteratura e potenziali vantaggi della chirurgia gastrica robotica

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Roma 9-10-11 Marzo 2016
Palazzo dei Congressi



La chirurgia gastrica oncologica rappresenta uno dei campi di maggiore interesse e sviluppo nell'ambito della chirurgia mininvasiva e in particolare oggi robotica.

Overview

LAPAROSCOPIC SURGERY

The number of laparoscopic gastrectomies is increasing

Laparoscopy has been evaluated as an alternative to open surgery with the potential benefits of decreased operative morbidity and reduced recovery times

ROBOTIC SURGERY

The benefit has only been shown by small comparative studies

Meta-analyses confirm benefits in distal gastrectomy, though some concerns remain regarding long-term outcomes and the possibility for reduced nodal harvest

Robotic surgery is not even mentioned in the current guidelines

The evidence is still weak to be considered as standard procedures in daily practice

J Gastric Cancer 2013;13(2):136-148 • <http://dx.doi.org/10.52092/jgc.2013.13.136> Original Article

Robotic versus Laparoscopic versus Open Gastrectomy: A Meta-Analysis

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PLOS ONE

Efficacy Evaluation of Subtotal and Total Gastrectomies in Robotic Surgery for Gastric Cancer Compared with that in Open and Laparoscopic Resections: A Meta-Analysis

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Molti centri hanno progressivamente pubblicato le proprie esperienze e casistiche, dando modo agli autori di revisioni sistematiche e metanalisi di provare a definire il ruolo della chirurgia robotica confrontandola con la laparoscopia tradizionale e la chirurgia open.

Tuttavia, l'attuale livello di evidenza è ben lontano dal poter considerare queste procedure nella comune pratica chirurgica. Le linee guida attuali descrivono la laparoscopia come una possibile alternativa alla chirurgia open nell'early gastric cancer, mentre la chirurgia robotica possiede intrinseci vantaggi tecnologici, ma la ricerca non è stata ancora in grado di verificare questi vantaggi tramite studi con un adeguato livello di evidenza.

Robotic Gastrectomy

- Patient position
- Port placement



- Robotic Surgeon and Assistant position
- Robot-docking



Procedure performed by Dr. Parisi
St. Mary's Hospital of Terni

La chirurgia robotica ha rivoluzionato il modo di pensare e praticare la chirurgia mininvasiva, determinando un'evoluzione della tradizionale laparoscopia.

Robotic Gastrectomy: Skill

What skills can be improved with robotic technology?

The robotic surgery system facilitates the process of performing laparoscopic surgery and provides:

- Three dimensional (3D)- image
- Motion scaling
- Tremor filtering
- Coaxial alignment of the eyes, hands, and tool tip image.
- An intuitive translation of the instrument handle to the tip movement, thus eliminating the mirror image effect.
- An internal articulated endoscopic wrist, providing an additional three degrees of freedom.

This computer-enhanced surgical system thus allows surgeons to overcome various difficulties during endoscopic surgery:

- Lymphadenectomy include LN no. 8a, 9, 11p, 11d, 12a
- Isolation of diaphragmatic crura
- Lymphadenectomy in obese and bleeding control
- Esophagojejunal reconstruction

- Jiang ZW, Liu J, Wang G, Zhao K, Zhang S, Li N, Li JS: Esophagojejunostomy reconstruction using a robot-sewing technique during totally robotic total gastrectomy for gastric cancer. Hepatogastroenterology 2015, 62(138):323-326.
- Kim MC, Heo GU, Jung GJ: Robotic gastrectomy for gastric cancer: surgical techniques and clinical merits. Surg Endosc 2010; 24:610-615.
- Lee J, Kim YM, Woo Y, Obama K, Noh SH, Hyung WJ: Robotic distal subtotal gastrectomy with D2 lymphadenectomy for gastric cancer patients with high body mass index: comparison with conventional laparoscopic distal subtotal gastrectomy with D2 lymphadenectomy. Surg Endosc 2015.

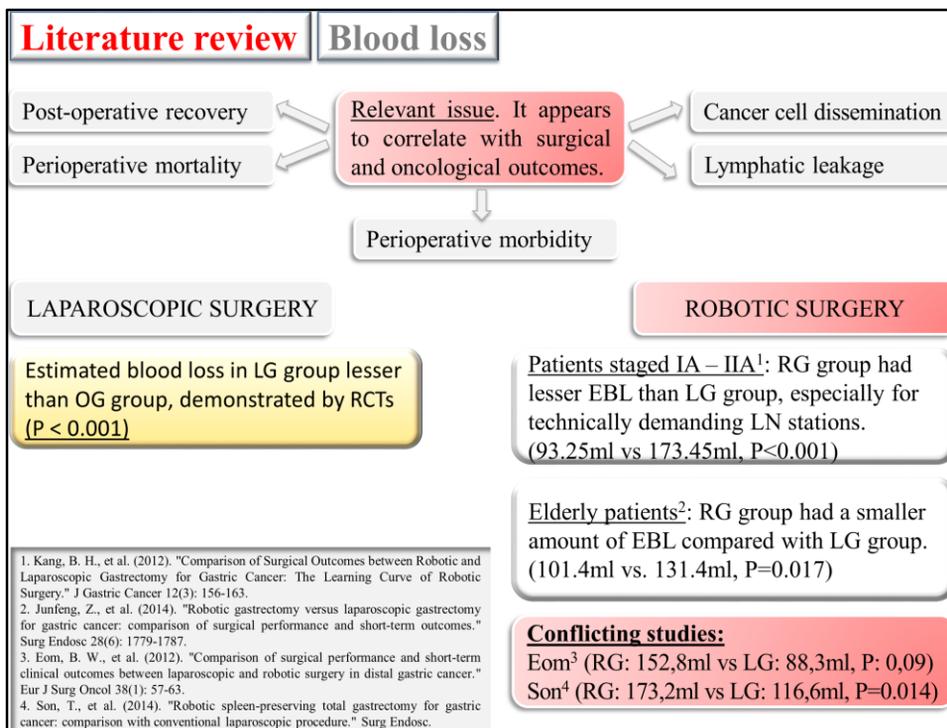
I chirurghi possono superarne i limiti nei movimenti di dissezione e di sutura che sono elementi chiave quando si deve realizzare una estesa linfadenectomia e la fase ricostruttiva.

Molte questioni sono però oggetto di dibattito.

Literature review**Lymph-node dissection**

	TYPE	SAMPLES (NO.)	D2 PROCEDURES (NO.)	RETRIEVED LN (MEAN)	P VALUE
Kim KM	RG Vs LG Vs OG	436 / 861 / 4542	Not reported	40,2 / 37,6 / 40,5	<0,001
Huang	RG Vs LG Vs OG	39 / 64 / 586	34 / 12 / 516	32 / 26 / 34	<0,001
Caruso	RG Vs OG	29 / 120	29 / 120	28 / 31,7	0,02
Kim MC	RG Vs LG Vs OG	16 / 11 / 12	14 / 8 / 12	41,1 / 37,4 / 43,3	0,3
Patriti	RG Vs OG	14 / 13	14 / 13	28,1 / 23,7	NS
Pugliese	RG Vs LG	31 / 25	31 / 25	18 / 52	not reported
Woo	RG Vs LG	236 / 591	105 / 279	39 / 37,4	0,3
Eom	RG Vs LG	30 / 62	20 / 34	30,2 / 33,4	0,1
Hyun	RG Vs LG	38 / 83	14 / 18	32,8 / 32,6	0,9
Junfeng	RG Vs LG	120 / 394	Not reported	34,6 / 32,7	0,01
Kang	RG Vs LG	100 / 282	Not reported	Not reported	Not reported
Kim HI	RG Vs LG	172 / 481	74 / 235	37,3 / 36,8	0,8
Noshiro	RG Vs LG	21 / 160	8 / 81	44 / 40	0,2
Park	RG Vs LG	30 / 120	Not reported	34 / 35	0,6
Son SY	RG Vs LG	21 / 42	8 / 20	46,5 / 39,7	0,6
Son T	RG Vs LG	51 / 58	51 / 58	47,2 / 42,8	0,2
Song	RG Vs LG	20 / 20	4 / 10	35,3 / 31,5	0,3
Suda	RG Vs LG	88 / 438	52 / 207	40 / 38	0,1
Uyama	RG Vs LG	25 / 225	18 / 225	44,3 / 43,2	0,7
Yoon	RG Vs LG	36 / 65	Not reported	39,4 / 42,8	0,2

Primo fra tutti la necessità di garantire un intervento oncologicamente radicale. La corretta esecuzione della linfadenectomia è considerato il più rilevante fattore influenzante la sopravvivenza a lungo termine. La laparoscopia se da una parte ha dimostrato in studi randomizzati di garantire la rimozione del numero minimo di 15 linfonodi richiesto dalle linee guida, tuttavia risulta una differenza significativa in favore della chirurgia open nel numero totale di linfonodi rimossi. La chirurgia robotica promette una migliore dissezione linfonodale. Bisogna sottolineare che il reale confronto da prendere in considerazione in questo ambito è però con l'approccio attualmente di riferimento, cioè quello open. Tuttavia se ad oggi molti sono gli studi comparativi con la laparoscopia, la tabella evidenzia l'insufficienza di studi che confrontano la chirurgia robotica con quella tradizionale.



Fra gli outcomes intraoperatori la perdita ematica, che inoltre è ritenuta correlare strettamente con gli outcomes postoperatori, risulta nella maggior parte degli studi a favore della chirurgia mininvasiva. Questo ha ottenuto un alto grado di significatività statistica per la laparoscopia nella metanalisi di studi randomizzati di Vinuela, mentre per la chirurgia robotica sembra esserci una generale concordanza nel rilevare una minore perdita ematica sia rispetto alla chirurgia open che laparoscopica, sebbene esistano anche studi in contrasto.

Literature review

Complications

ROBOTIC VS LAPAROSCOPIC GASTRECTOMY

Hyun et al. reported the total complications, assessed by the C-D classification system, were not significantly different between the RG and LG groups ($P = 0,36$).

The RG group had a higher total number of complications than the LG group, but most of these complications were minor and could be treated nonsurgically.

The LG group had more major complications that required surgical, radiologic, or endoscopic intervention than the RG group.

Son et al. confirmed a similar incidence of postoperative complications in RG and LG ($P = 0.37$).
The severity was similar between the two groups ($P = 0.88$).

Park et al. showed postoperative complications occurred more frequently in the RG group than the LG group (17% vs 7,5%, $P = 0,12$), although most were minor and managed conservatively.

The incidence of severe complications requiring an additional invasive procedure did not differ significantly between the groups ($P=0,25$).

Hyun, M. H., et al. (2013). "Robot versus laparoscopic gastrectomy for cancer by an experienced surgeon: comparisons of surgery, complications, and surgical stress." *Ann Surg Oncol* 20(4): 1258-1265.
Son, T., et al. (2014). "Robotic spleen-preserving total gastrectomy for gastric cancer: comparison with conventional laparoscopic procedure." *Surg Endosc*.
Park, J. Y., et al. (2012). "Surgical stress after robot-assisted distal gastrectomy and its economic implications." *Br J Surg* 99(11): 1554-1561.

Riguardo il periodo postoperatorio ricordiamo che il KLASS trial non ha evidenziato differenze tra la laparoscopia e la chirurgia open nell'overall complications, ma altri studi hanno evidenziato una riduzione nelle complicitanze mediche e chirurgiche minori.

Gli studi sulla chirurgia robotica per contro si sono dimostrati inconsistenti nel dimostrare differenze con l'approccio laparoscopico.

ROBOTIC VS LAPAROSCOPIC VS OPEN GASTRECTOMY

Study or subgroup	RG			LG			Weight (%)	Mean difference IV, random, 95% CI	Mean difference IV, random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Kim et al. ¹⁷	5.1	0.30	16	6.5	0.80	11	27.9	-1.40 [-1.90, -0.90]	
Pugliese et al. ¹⁸	10.0	3.00	16	10.0	2.60	48	17.3	0.00 [-1.64, 1.64]	
Yoon et al. ¹⁹	8.8	3.30	36	10.3	10.80	65	9.4	-1.50 [-4.34, 1.34]	
Woo et al. ²⁰	7.7	17.20	236	7.0	5.70	591	12.7	0.70 [-1.54, 2.94]	
Eom et al. ²¹	7.9	0.27	30	7.8	0.27	62	29.6	0.10 [-0.02, 0.22]	
Huang et al. ²³	11.3	14.40	39	17.2	13.30	64	3.2	-5.90 [-11.47, -0.33]	
Total (95% CI)			373			841	100.0	-0.60 [-1.66, 0.45]	

Heterogeneity: Tau²=0.98; chi²=39.17, df=5 (P<0.00001); I²=87%
 Test for overall effect: Z=1.12 (P=0.26)

Study or subgroup	RG			OG			Weight (%)	Mean difference IV, random, 95% CI	Mean difference IV, random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Kim et al. ¹⁷	5.1	0.3	16	6.7	1.4	12	49.0	-1.60 [-2.41, -0.79]	
Caruso et al. ²²	9.6	2.8	29	13.4	8.5	120	37.0	-3.80 [-5.63, -1.97]	
Huang et al. ²³	11.3	14.4	39	16.5	13.6	586	14.0	-5.20 [-9.85, -0.55]	
Total (95% CI)			84			718	100.0	-2.92 [-4.94, -0.89]	

Heterogeneity: Tau²=2.01; chi²=6.47, df=2 (P=0.04); I²=69%
 Test for overall effect: Z=2.82 (P=0.005)

Kim and Woo assessed that patients who underwent robotic gastrectomy could be discharged at an earlier date than patients who underwent open or laparoscopic gastrectomy.

Woo identified a significantly larger percentage of patients in the robotic group discharged by postoperative day 5 (48.8% of the LGS group vs. 61.0% of the RGS group; P = 0.04).

Marano, A. et al. (2013). "Robotic versus Laparoscopic versus Open Gastrectomy: A Meta-Analysis." jgc 13(3): 136-148.

Complessivamente, la chirurgia mininvasiva ha dimostrato vantaggi significativi in termini di durata della degenza postoperatoria. Alcune evidenze (Kim e Woo) riportano inoltre che quei pazienti sottoposti a gastrectomia robotica possono essere dimessi ancora più precocemente rispetto alla laparoscopia tradizionale. Anche in questo caso, il ridotto numero di studi e l'estrema eterogeneità degli approcci adottati non supportano efficacemente questa conclusione.

Literature review

Post-operative recovery

ROBOTIC VS LAPAROSCOPIC VS OPEN GASTRECTOMY

Manually handling organs during gastrectomy is an important contributor to the inflammatory response

The smaller robot instruments may induce less inflammation than other approaches

Postoperative bowel recovery in the robotic group may occur sooner

Robot-sewn intracorporeal anastomosis is feasible and permits small wounds that create less pain, increasing patients' satisfaction.

Junfeng reported RGS is comparable to LGS regarding time of first flatus, days to eating a liquid diet, and length of hospital stay.

Song reported that patients in the RGS group tended to ambulate earlier, felt less pain, and were able to be discharged from hospital earlier.

Son showed postoperative restoration of bowel function, resumption of oral intake and hospital stay, were slightly in favor of laparoscopy.

Park reported that postoperative fluid discharge from the drain was reduced in patients who received RGS.

Kang reported significant longer average hospital stays in RGS group than LGS group (9.81 days vs. 8.11 days, $P = 0.042$).

Nuovi studi devono essere realizzati per definire il ruolo dei diversi approcci, vantaggi e svantaggi.

Come osservato da Hiki, la manipolazione dei visceri durante la gastrectomia è uno dei fattori più rilevanti nel determinare la risposta infiammatoria postoperatoria. Lo strumentario microchirurgico robotico potrebbe quindi determinare una riduzione di questa risposta infiammatoria rispetto ad altri approcci, permettendo una più rapida ripresa della funzionalità intestinale.

Literature review

Reconstruction

The possibility of safely achieving intracorporeal anastomosis in place of extracorporeal procedures is currently being debated.

Advantages and limits have not been highlighted by current studies.

Robots can help surgeons because of the precise three-dimensional view and the instruments with seven degrees of freedom.

Hur H, Kim JY, Cho YK, Han SU. Technical feasibility of robot-sewn anastomosis in robotic surgery for gastric cancer. *J Laparoendosc Adv Surg Tech A* 2010; 20: 693-7.

Lack of scientific evidence

Indubbiamente uno degli aspetti tecnici emergenti e affascinanti in chirurgia robotica è la possibilità di realizzare la fase ricostruttiva dell'intervento interamente con anastomosi intracorporee.

In questo contesto la chirurgia robotica potrebbe dimostrare una netta superiorità rispetto alla laparoscopia, ma questo aspetto non è stato adeguatamente approfondito.

Literature review**Reconstruction: ROBOTIC TOTAL GASTRECTOMY**

	YEAR	TYPE	SUBJECT	COUNTRY	INSTITUTION	PERIOD	NO.
Jiang	2015	Retrospective CS	RAG	China	Nanjing University Medical College	2010-2012	65
Kim KM	2012	nonRCT	RAGvsLGvsOG	Korea	Yonsei University College of Medicine	2005-2010	109
Son T.	2014	nonRCT	RTG vs LTG			2005-2010	51
Woo	2011	nonRCT	RAG vs LG			2005-2009	62
Song	2009	Prospective CS	RAG			2005-2007	33
Park	2013	Retrospective CS	RAG			2009-2012	46
Yoon	2012	nonRCT	RTG vs LTG	Korea	National Cancer Center	2009-2011	36
Kang	2012	nonRCT	RAG vs LG	Korea	Ajou University School of Medicine	2008-2011	16
Hur	2010	Retrospective CS	RAG			2010	2
Hyun	2013	nonRCT	RAG vs LG	Korea	Korea University Anam Hospital	2009-2010	9
Son SY	2012	nonRCT	RAG vs LG	Korea	Seoul University Bundang Hospital	2007-2011	1
Junfeng	2014	nonRCT	RAG vs LG	China	Third Military Medical University	2010-2013	26
Liu	2013	Prospective CS	RAG	China	Subei People's Hospital of Jiangsu	2011-2013	54
Giulianotti	2003	Retrospective CS	RAG	Italy	Misericordia Hospital of Grosseto	2000-2002	10
Coratti	2015	Retrospective CS	RAG	Italy			38
D'Annibale	2011	Retrospective CS	RAG	Italy	S. Giovanni Addolorata Hospital	2004-2009	11
Caruso	2011	nonRCT	RAG vs OG	Italy	Hospital of Spoleto	2006-2010	12
Suda	2014	nonRCT	RAG vs LG	Japan	Fujita Health University	2009-2012	30
Huang	2012	nonRCT	RAGvsLGvsOG	Taiwan	Taipei Veterans General Hospital	2010-2012	7
Vasilescu	2012	Retrospective CS	RAG	Romania	Fundeni Clinical Institute	2008-2012	19
Zawadzki	2014	CR	RAG	Poland	Wroclaw Medical University	2014	1
Parisi	2015	Prospective CS	RTG	Italy	St. Mary's Hospital of Terni	2014-2015	22
TOTAL							466

In letteratura un totale di 22 studi di autori provenienti da 16 istituti hanno riportato l'esecuzione della gastrectomia totale con approccio robotico.

11 sono comparativi, gli altri sono case series e personal experiences.

Solo 4 studi riguardano esclusivamente la gastrectomia totale. Gli altri riportano outcomes di sottogruppi all'interno di un'analisi più estesa che comprende anche la gastrectomia distale.

Nel complesso si possono rilevare 466 procedure.

Literature review Reconstruction: ROBOTIC TOTAL GASTRECTOMY

	Robot - Assistance			Type	E-J Anastomosis	Anastomosis performance	Site of minilaparotomy	Operative /Clinical Data	Patient/ tumor details
	Lymphadenectomy	Stomach mobilization	Reconstruction						
Jiang	performed	performed	Performed	Robot-Y	EXTRA	Circular stapler	Not provided	provided	Provided
Kim KM	Not provided	Not provided	Not provided	Robot-Y	INTRA	Robot-sewn	Not provided	lack	Lack
Son T.	performed	performed		Robot-Y	EXTRA	Circular stapler	Upper midline	provided	Provided
Woo	performed	performed		Robot-Y	INTRA LAP	Circular stapler	Left lower port	lack	Lack
Song	performed	performed		Robot-Y	EXTRA	Not provided	Not provided	lack	Lack
Park	performed	performed		Robot-Y	INTRA LAP	Circular stapler	Upper midline	provided	Lack
Yoon	performed	performed		Robot-Y	EXTRA	Not provided	Upper midline	provided	Provided
Kang	performed	performed	Performed	Robot-Y	EXTRA	Circular stapler	Upper midline	lack	Lack
Hur	performed	performed	Performed	Robot-Y	INTRA	Robot-sewn	Not provided	lack	lack
Hyun	performed	performed	Not provided	Robot-Y	EXTRA	Circular stapler	Upper midline	lack	lack
Son SY	performed	performed		Robot-Y	INTRA	Not provided	Umbilical port	lack	lack
Junfeng	performed	performed		Robot-Y	EXTRA	Not provided	Not provided	lack	lack
Liu	performed	performed	performed	Robot-Y	EXTRA	Circular stapler	Upper midline	provided	provided
Giulianotti	performed	performed	performed	Robot-Y	INTRA	Robot-sewn	Camera port	lack	lack
Coratti	performed	performed	performed	Robot-Y	INTRA	Circular stapler	Not provided	lack	lack
D'Annibale	performed	performed	performed	Robot-Y	INTRA	Robot-sewn	Not provided	provided	provided
Caruso -Patrii	performed	performed	performed	Robot-Y	INTRA	Circular stapler	Suprapubic	lack	lack
Suda	performed	Performed	performed	Robot-Y	INTRA	Circular stapler	Upper midline	lack	lack
Huang	Performed	Performed	performed	Robot-Y	INTRA	Linear stapler	Not provided	provided	provided
Vasilescu	performed	Performed	Performed	Robot-Y	INTRA LAP	Circular stapler	Periumbilical	lack	lack
Parisi	performed	Performed	performed	Robot-Y	INTRA	Circular stapler	Not provided	Lack	lack
				Robot-Y	INTRA	Robot-sewn	McBurney	provided	Provided

Un'analisi più approfondita evidenzia che l'assistenza del robot è stata utilizzata in tutti gli interventi per la mobilizzazione e la linfadenectomia estesa, ma riguardo la fase ricostruttiva sono riportati una grande varietà di soluzioni tecniche, producendo un'estrema eterogeneità dei dati.

Solo 10 studi riportano in maniera dettagliata l'esecuzione di anastomosi intracorporee.

Quattro studi sottolineano nei metodi che il team chirurgico ha preferito svolgere la parte ricostruttiva dopo aver undocked il robot e quindi in laparoscopia.

L'altro elemento da considerare è che solo sette studi riportano dati sulle caratteristiche dei pazienti e i risultati ottenuti. Questo è causato dall'assenza di analisi di sottogruppo in quegli articoli che riportano unificati gli outcomes di gastrectomie subtotali e totali.

ROBOTIC TOTAL GASTRECTOMY

Extracorporeal anastomoses

Minilaparotomy (5 - 6 cm) through which the ends that need to be anastomosed are brought out and continuity of the digestive tract is reestablished usually with the aid of a circular stapler.

- Son T.
- Woo
- Song
- Park
- Yoon
- Kang
- Hyun
- Son SY
- Jiang
- Junfeng

Intracorporeal Anastomosis

Avoid the laparotomy and imply performing anastomosis under video - assistance by different solutions.

Laparoscopic assistance

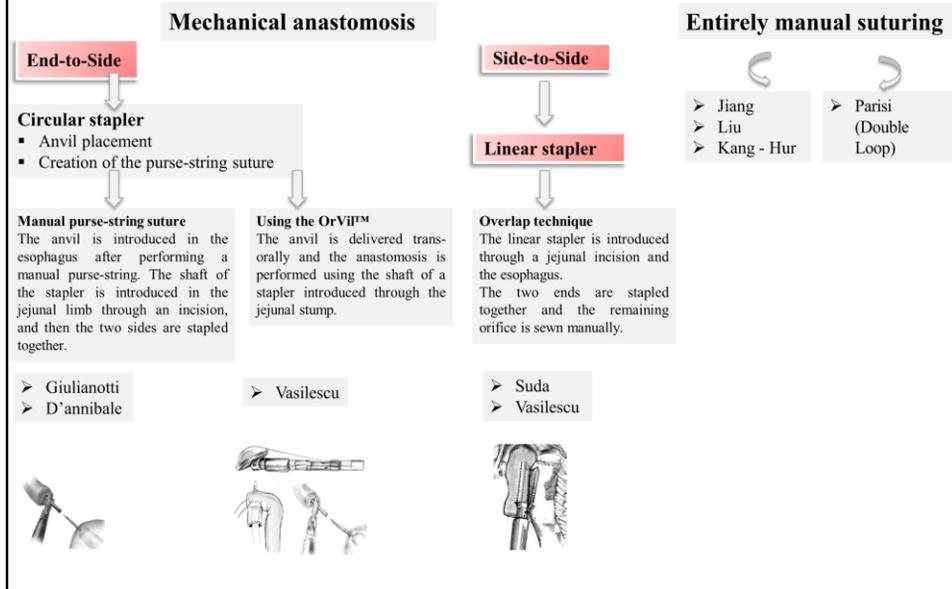
- Son T.
- Woo
- Song
- Huang

Robotic assistance

- Parisi
- Jiang
- Liu
- Kang
- Hur
- Hyun
- Giulianotti
- D'annibale
- Patriiti
- Suda
- Vasilescu

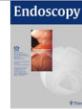
La fase ricostruttiva può essere suddivisa in due categorie principali in base all'approccio: anastomosi extracorporea e intracorporea. Quest'ultima può essere assistita dalla laparoscopia o dal sistema robotico.

ROBOTIC TOTAL GASTRECTOMY



In ogni caso la domanda è: come eseguire l'anastomosi esofago-digiunale?
 In letteratura, nella maggior parte dei casi, è riportata l'esecuzione di anastomosi meccaniche, mediante suturatrici circolari introdotte da una minilaparotomia di servizio. Altre soluzioni includono l'Orvil e l'overlap technique.
 Solo Quattro autori riportano l'esecuzione di anastomosi manuali robotiche.

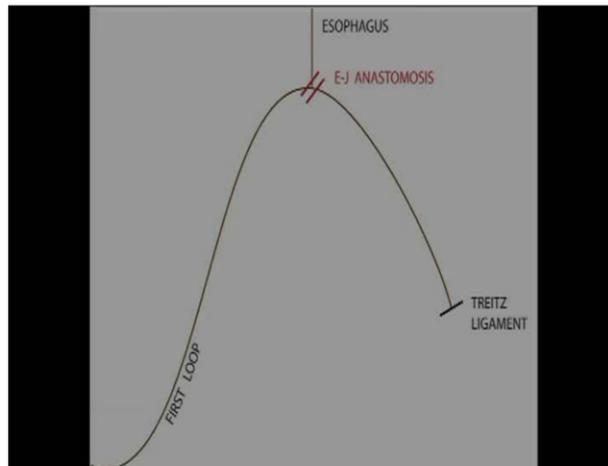
The Double Loop Technique with Robot-Sewn Eso-Jejunostomy



The “Double loop” technique is a simplification of the traditional technique of construction of the Roux-limb:

- The first loop of bowel is brought up antecolic and an End-to-Side esophago-jejunal anastomosis is performed with the robot.
- A second loop of bowel, distal from the esophago-jejunal anastomosis is brought up to the afferent first loop and the enteroenteric anastomosis is performed manually or mechanically.
- Finally the bowel is interrupted between the EJ and the EE anastomosis to create the Roux-en-Y.

Procedure performed by Dr. Parisi at the St. Mary's Hospital of Terni



Parisi, A., et al., *Robotic Total Gastrectomy With Intraoperative Robot-Sewn Anastomosis: A Novel Approach Adapting the Double-Loop Reconstruction Method*. *Medicine* (Baltimore), 2015. 94(49): p. e1922.

Parisi, A., et al., *Robotic double-loop reconstruction method following total gastrectomy*. *Endoscopy*, 2016. 48 Suppl 1: p. E55-6

In particolare la tecnica proposta nello studio di Parisi, prevede un approccio double loop: un primo loop intestinale proveniente dal Treitz viene portato in prossimità dell'esofago sezionato, in modo da avere la porzione biliare sul versante sinistro e quella alimentare sul versante destro.

È quindi realizzata l'anastomosi esofagodigiunale termino-laterale: si procede con un primo strato esterno posteriore mediante punti staccati tra la sierosa digiunale e la muscolare esofagea; poi l'esofago e la parete intestinale sono aperti e sono eseguite due semicontinue una posteriore e una anteriore; si completa con il secondo strato anteriore.

Si segue poi il decorso dell'ansa alimentare fino a raggiungere una distanza di circa 40cm dalla prima anastomosi identificando il secondo loop intestinale che viene portato superiormente e appaiato al versante biliare del primo loop in modo da realizzare l'anastomosi digiuno-digiunale. Al termine il double loop è trasformato in una Roux mediante interruzione della continuità tra le due anastomosi con un colpo di suturatrice lineare.

Future Perspectives

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ELSEVIER

Review

Current status of minimally invasive surgery for gastric cancer: A literature review to highlight studies limits*

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Surgery
Volume 157, Issue 4, April 2015, Pages 830–831

Letter to the Editor

Establishing a multi-institutional registry to compare the outcomes of robotic, laparoscopic, and open surgery for gastric cancer

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WHAT KIND OF STUDY?

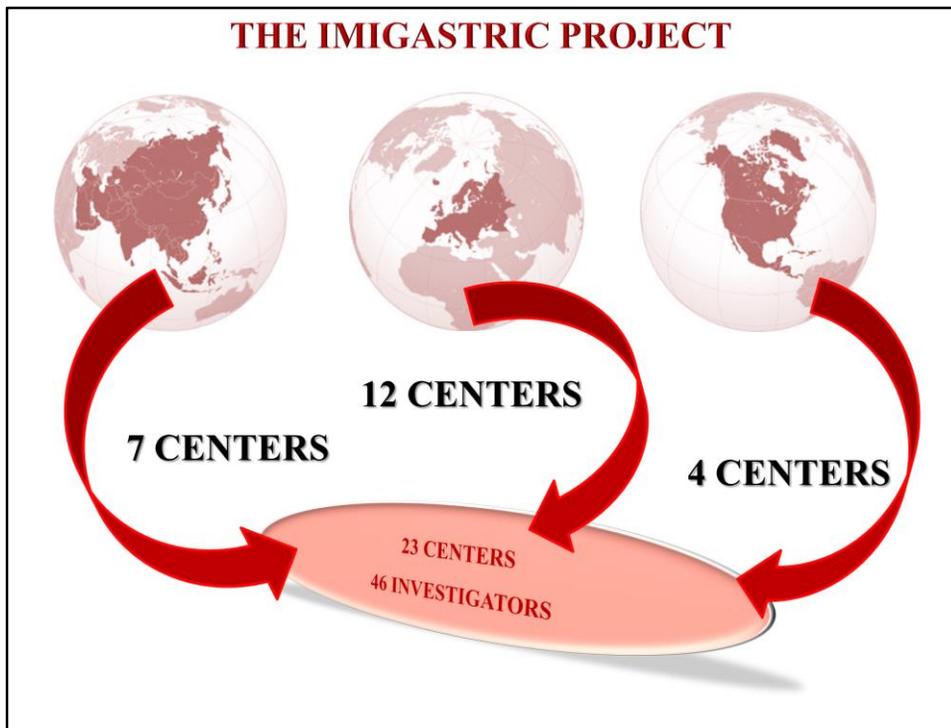
INTERNATIONAL STUDY GROUP ON MINIMALLY INVASIVE SURGERY FOR GASTRIC CANCER

Open Access Protocol

BMJ Open **Robotic, Laparoscopic and Open Surgery for Gastric Cancer Compared on Surgical, Clinical and Oncological Outcomes: Establishing a Multi-Institutional Registry. Study Protocol of the International Study Group on Minimally Invasive surgery for Gastric Cancer - IMIGASTRIC**

Amikare Parisi, Zhi-Wei JIANG, Shu ZHANG, Ninh T. Nguyen, Daniel Reim, Steven T. Brower, Juan-Santiago Azagra, Olivier Facy, Orhan Altinoglu, Patrick G. Jackson, Hironori Tsujimoto, Yukinori Kurokawa, Lu ZANG, Natalie G. Coburn, Pei-Wu YU, Ben ZHANG, Feng QI, Mario Annechiarico, Francesco Bazzocchi, Andrea Avanzini, Johan Cagniere, Dennis Pezet, Alexander Novotny, Martine Goergen, Jean-Baptiste Lequeu, Tunc Eren, Metin Leblebici, Waddah Al-Rafeie, Shuji Takiguchi, Junjun MA, Yong-Liang ZHAO, Tong LIU, Andrea Coratti, Jacopo Desiderio

Come abbiamo visto, nonostante i potenziali vantaggi della chirurgia robotica, è ancora molta la ricerca da sviluppare in questo campo e la comunità scientifica si chiede quali strategie adottare in futuri studi.



Proprio per questo nell'aprile 2014 è stata avviata dal Dr. Parisi, presso il centro di chirurgia digestiva mininvasiva dell'azienda ospedaliera di Terni, la fase preliminare di un progetto volto ad individuare gli istituti interessati alla raccolta di dati in un registro internazionale.

IMIGASTRIC

Institutions reached an agreement

- Principles of the study
- Objectives
- Data to be collected
- Software tools



Join databases

Compare all the current surgical approaches

Contribution on gastric cancer research

www.imigastric.com

ClinicalTrials.gov PRS
Protocol Registration and Results System

**DEVELOPMENT AND SHARING
A STUDY PROTOCOL**

BMI Open Robotic, Laparoscopic and Open Surgery for Gastric Cancer Compared on Surgical, Clinical and Oncological Outcomes: Establishing a Multi-Institutional Registry. Study Protocol of the International Study Group on Minimally Invasive surgery for Gastric Cancer - IMIGASTRIC

Dopo aver condiviso un protocollo di studio ed aver raggiunto un'intesa si è proceduto allo sviluppo di un registro completamente informatizzato e accessibile online denominato IMIGASTRIC.

IMIGASTRIC



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IMIGASTRIC

General study design

OVERALL PURPOSE

Develop and maintain an ongoing comprehensive multi-institutional database comprising of information regarding surgical, clinical and oncological features of patients undergoing surgery for gastric cancer with robotic, laparoscopic or open approaches and subsequent follow-up at participating centers.

The Main Objectives

- To determine the surgical, clinical, and oncological outcomes in both the short and long term
- To compare results according to the type of intervention, device used and manner of execution of different surgical phases
- To relate results of different surgeries with baseline characteristics of patients and stage of disease

L'obiettivo generale è quello di raccogliere dati dettagliati e standardizzati relativi alle procedure adottate, decorso clinico, follow-up a breve e lungo termine di pazienti sottoposti a chirurgia gastrica con approccio Robotico, laparoscopico, open.

IMIGASTRIC

General study design

TYPE OF STUDY

Different steps with an increasing level of scientific evidence were planned.

First Step: Retrospective study – Chart Review

Data of subjects with gastric cancer treated at the participating centers. Information gathered will be obtained from existing records, diagnostic tests and surgical interventions description

Second Step: Prospective Trial

Enrollment will be opened to newly identified subjects into the registry upon diagnosis and treatment in a prospective manner.

La raccolta dati, ufficialmente partita a fine Maggio 2015 è attualmente in corso in senso retrospettivo, mentre la fase prospettica ha ricevuto da poco l'approvazione del comitato etico da parte dell'istituto promotore e sarà quindi avviata a breve.

METHODS

Data collection

➤ *Patient Demographics*

- Sex, age, BMI, ASA score, concomitant illness, previous abdominal surgery.

➤ *Surgical Procedure details*

- Type of surgical approach: open, laparoscopy, robotic
- Gastric resection and type of reconstruction
- Anastomosis approach: intra-corporeal, extra-corporeal
- Anastomosis performance: linear stapler, circular stapler, hand-sewn, robot-sewn
- Extent of lymphadenectomy: D1, D1+, D2, D2+
- Duration of surgery, blood loss, intraoperative complications
- Number of retrieved lymph nodes, margin free of disease or infiltrated.

➤ *Tumor characteristics*

- Tumor location: Upper third, Middle third, Lower third.
- Depth of invasion (T classification), lymph node status (N classification), AJCC pathological stage, Histological type and Lauren classification

METHODS

Data collection

- *Post-operative clinical findings*
 - Time to start oral intake
 - Resumption of bowel function
 - Length of postoperative hospital stay
- *Post-operative complications*
 - Type and grade of in-hospital complications
 - Surgical complications after discharge
- *Follow-up details*
 - Patient alive, not alive or lost at follow-up
 - Disease-free or not at follow-up
 - Time to onset of recurrence and site of recurrence

TOOLS

The imigastric software

IMIGASTRIC STUDY [DEMO version]

Username:
Password:
Login

IMIGASTRIC
Center No.: 1
St. Maria Hospital
AMIBAR PARTI
AMIBAR PARTI
ACCOUNT
Log out

Home All Operations Patients Customers Publications Support

Patients

PATIENTS LIST PATIENTS SEARCH

Patient	Serial	Serial	Serial	P.D. close	P.D. day	Indicate P.D.	Configuration	Indicate
0001-0001	1010101010	<input checked="" type="checkbox"/>						
0001-0002	1010101010	<input checked="" type="checkbox"/>						
0001-0003	1010101010	<input checked="" type="checkbox"/>						

SOFTWARE ENGINEERING

PLANNING ANALYZE DESIGN
VALIDATION AND VERIFICATION PROGRAMMING
LOW-LEVEL-TEST HIGH-LEVEL-TEST

IMIGASTRIC
Username:
Password:
Login

Timeline:

- November 2014 - January 2015: Planning stage of the software
- February 2015 - April 2015: Evaluation and testing of the software, via access to a demo version by all the investigators
- May 14, 2015: Opening of the IMIGASTRIC registry

Centers are accredited for entering data of patients treated from January 1, 2000 to May 14, 2015

You can access the login page by clicking here

First Interim Data Analysis

March 6, 2016

Raw data from June to December 2015

was extracted and analyzed.

The analysis was performed considering the following sections:

Overview of the registry

- total number of entered patients
- total number of patients in the analysis
- age
- sex
- BMI
- ASA
- smoker
- concomitant illness
- previous abdominal surgery
- neo-adjuvant chemotherapy
- neo-adjuvant radiotherapy
- tumor location
- stage
- type of gastrectomy
- extend of gastrectomy
- extend of lymphadenectomy
- type of surgical approach

Patient characteristics for surgical approach

- age
- sex
- BMI
- ASA
- smoker
- concomitant illness
- neo-adjuvant chemotherapy
- neo-adjuvant radiotherapy

Surgical procedure details

- type of gastric resection
- type of reconstruction
- anastomosis performance
- anastomosis approach
- type of lymphadenectomy
- operative time
- EBL
- Number of retrieved lymph nodes
- length of incision
- robotic docking time
- conversion to open surgery
- site of minilaparotomy
- intraoperative complications
- intraoperative death
- margin status
- residual tumor
- intraoperative blood transfusion
- placement of intra-abdominal drain

Tumor characteristics

- tumor location
- stage
- T classification
- N classification
- histology

Post-operative clinical findings

- enhanced recovery after surgery (ERAS) protocols adopted
- length of postoperative hospital stays
- patient mobilisation (post-operative day (POD) number)
- liquid diet (POD number)
- soft solid diet (POD number)
- resumption of peristalsis (POD number)
- first flatus (POD number)
- drain removal (POD number)
- length of intravenous antibiotic use
- length of intravenous analgesic use
- postoperative blood transfusion
- postoperative complications
- complications after discharge
- death for complication after discharge

Follow-up details

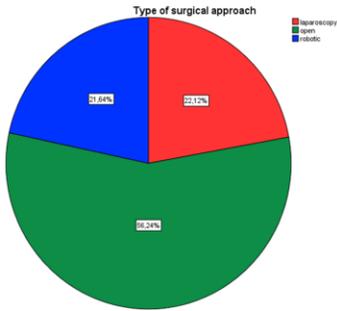
- adjuvant chemotherapy
- adjuvant radiotherapy
- survival analysis
- overall survival
- survival trend up to 60 months
- survival rate at 1, 3, 5 years

È un piacere per me annunciare, in questa sede, che è stata inoltre effettuata in queste settimane una prima estrazione dei dati sui primi sei mesi di lavoro e una prima Interim data analysis dello studio è stata realizzata. Questa sarà presentata ufficialmente al KINGCA di Seul il prossimo 22 Aprile e ha messo in evidenza le grandi potenzialità di questo registro.

First Interim Data Analysis

Total number of entered patients 1211
Total number of patients in the analysis (first 6 months of data entry) 1026

SURGERY	
Open	558
Laparoscopic	232
Robotic	236



Outcomes		Std.		P value
		Mean	Deviation	
Operative time (min.)	Robotic _a	348,73	95,76	<0.001
	Laparoscopic _b	207,01	87,42	
	Open _b	204,48	67,63	
EBL (ml)	Robotic _a	137,93	77,31	<0.001
	Laparoscopic _b	95,95	113,72	
	Open _c	203,92	158,23	
No. of LN retrieved	Robotic _a	27,47	12,72	<0.001
	Laparoscopic _b	21,39	13,05	
	Open _c	29,59	14,44	

Intraoperative complications

	laparoscopy	open	robotic
YES	4	8	3
	1,8%	1,4%	1,4%

Intraoperative death

	Laparoscopy	open	robotic
YES	1	2	0
	0,4%	0,3%	0,0%

Margin status

	laparoscopy	open	robotic
Free of disease	223 _{a, b}	550 _b	222 _a
	98,2%	95,3%	100,0%
R0	216 _{a, b}	530 _b	217 _a
	95,2%	91,9%	97,7%

First Interim Data Analysis

Outcomes		Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Min	Max	P value
					Lower Bound	Upper Bound			
Hospital stay (days)	Robotic	8,74	4,84	0,33	8,10	9,38	2,00	34,00	<0,001
	Laparoscopy	8,29	8,12	0,54	7,23	9,35	2,00	64,00	
	Open	13,91	9,20	0,38	13,16	14,66	5,00	99,00	
Mobilization (days)	Robotic	1,20	1,00	0,07	1,06	1,33	1,00	14,00	0,001
	Laparoscopy	1,70	1,60	0,11	1,48	1,91	1,00	12,00	
	Open	1,58	1,53	0,06	1,46	1,71	1,00	15,00	
Liquid diet (days)	Robotic	3,12	2,24	0,15	2,82	3,42	1,00	20,00	0,001
	Laparoscopy	3,53	2,66	0,18	3,18	3,88	1,00	16,00	
	Open	3,94	3,18	0,13	3,68	4,20	1,00	34,00	
Soft solid diet (days)	Robotic	4,18	2,01	0,15	3,88	4,47	1,00	16,00	0,001
	Laparoscopy	5,46	4,88	0,35	4,78	6,14	2,00	34,00	
	Open	6,04	6,51	0,33	5,38	6,70	3,00	64,00	
Resumption of peristalsis (days)	Robotic	1,79	1,14	0,08	1,64	1,95	1,00	10,00	0,008
	Laparoscopy	1,60	0,95	0,06	1,47	1,72	1,00	6,00	
	Open	1,84	0,93	0,04	1,76	1,91	1,00	7,00	
First flatus (days)	Robotic	3,37	1,33	0,09	3,20	3,55	1,00	10,00	0,089
	Laparoscopy	3,39	0,76	0,05	3,29	3,49	2,00	8,00	
	Open	3,53	1,03	0,04	3,45	3,61	1,00	10,00	
Drain removal (days)	Robotic	5,35	2,57	0,17	5,01	5,69	1,00	24,00	0,010
	Laparoscopy	5,90	3,57	0,24	5,43	6,37	3,00	29,00	
	Open	6,14	3,37	0,14	5,87	6,42	3,00	42,00	
Intravenous antibiotic use (days)	Robotic	3,24	3,48	0,24	2,77	3,71	0,00	27,00	0,817
	Laparoscopy	3,35	3,10	0,21	2,94	3,76	0,00	22,00	
	Open	3,43	3,92	0,16	3,10	3,75	0,00	46,00	
Intravenous analgesic use (days)	Robotic	3,12	1,55	0,12	2,89	3,35	0,00	8,00	0,009
	Laparoscopy	3,03	0,73	0,05	2,93	3,13	0,00	8,00	
	Open	3,40	1,76	0,09	3,23	3,58	1,00	22,00	

MORE INFORMATION



www.imigastric.com

Ulteriori informazioni sono disponibili al sito dello studio.