



## Meta analysis of robot-assisted versus conventional laparoscopic fundoplication in children

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### ARTICLE INFO

#### Article history:

Received 16 September 2013

Received in revised form 30 November 2013

Accepted 6 December 2013

#### Key words:

Robotic  
Robot-assisted  
Laparoscopy  
Gastro-esophageal reflux  
Fundoplication  
Children

### ABSTRACT

**Background:** Minimally invasive fundoplication may be performed using either a robot-assisted (RF) or conventional laparoscopic (LF) technique. Evidence comparing RF and LF in children remains unclear. This study aims to elucidate the comparative safety and efficacy of RF versus LF by systematic review and meta-analysis. **Methods:** Comparative studies investigating RF versus LF in children were identified from multiple electronic literature databases. Meta-analysis was performed using random effects modeling. Safety parameters investigated were post-operative morbidity and intra-operative conversions. Efficacy outcomes of interest were operative success, re-operation, post-operative complications, length of hospital stay (LOS), total operating time (OT), analgesia requirement, and cost.

**Results:** Six observational studies met inclusion criteria, reporting outcomes of 297 children. No randomized controlled trials were identified. Pooled analysis determined no statistically significant differences between RF and LF for conversions, OT, LOS, and post-operative complications. There was no standardized follow up beyond the early post-operative period to enable data synthesis for remaining outcomes of interest. Limited evidence indicates higher costs with RF.

**Conclusions:** Safety and short-term efficacy seem comparable between RF and LF in children. There is insufficient evidence to assess comparative effectiveness for many important procedure specific outcome measures. Higher quality and longer follow-up studies are required.

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Fundoplication is a high volume surgical procedure in the pediatric patient population. Indications are assorted and invariably related to symptoms or signs of gastro-esophageal reflux disease (GERD) [1]. Following the advent of endoscopic surgery, a minimally invasive approach to this anti-reflux procedure is now increasingly favored as standard of care [1].

Initial reports of laparoscopic anti-reflux surgery in infants and children were published in the early 1990's [2,3]. Almost ten years thereafter, robot-assisted minimally invasive surgery was first described in these age groups [4,5], and fundoplication remains the most prevalently reported application of this technology in pediatric general surgery [6]. Robotic technology offers putative patient benefits through a range of features that are felt to enhance the surgeon's ability to undertake minimally invasive surgery (MIS).

The role of robotic surgery in this setting remains unclear, generating a growing sentiment of polarized opinion amongst the surgical community, which is without a well-defined evidence base. The aim of this study is to critically appraise the literature comparing robot-assisted versus conventional laparoscopic MIS for fundoplica-

tion in order to further elucidate the comparative safety and efficacy of these techniques.

### 1. Methods

The study protocol was registered on the PROSPERO international prospective database of systematic reviews (CRD42013003971). Analysis was performed in accordance with recommendations outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement [7].

#### 1.1. Search strategy

Systematic literature searches were undertaken of PubMed and EMBASE electronic databases using the following search strategy ("Surgery, Computer-Assisted"[MeSH] OR "robotics"[MeSH] OR "da Vinci" OR "telerobotic" OR "telesurgery" OR "robotic surgery") AND ("Pediatrics"[MeSH] OR "Infant"[MeSH] OR "Child"[MeSH] OR "Adolescent"[MeSH]) AND ("Fundoplication"[MeSH] OR "Gastroesophageal reflux"[MeSH]). The search period was defined as June 2001 to June 2013 inclusively. The primary search was supplemented with searches of 1) PubMed related articles feature, 2) clinicaltrials.gov registry using the keyword "fundoplication", and 3) abstracts of the

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**Table 1**

Characteristics of studies included in the meta-analysis.

	Study design	Study period	n		Fundoplication	Min months follow up [mean (range)]	Surgeons	
			RF	LF			RF	LF
Ivascu 2004 [16]	RCC	2002–2003	17	34	Nissen	-	-	-
Lehnert 2006 [14]	PC	2001–2003	10	10	Thal	14 (-)	1	1
Copeland 2008 [13]	RCC	1994–2005	50	50	Nissen	1 (-)	7	3
Al-Bassam 2009 [11]	RC	2005–2008	25	25	Nissen	14 (1–48)	2	2
Anderberg 2009 [12]	RC	2006–2008	14	10	Nissen	12 (-)	1	2
Antao 2010 [15]	RC	1999–2009	19	33	Nissen	-	-	-

“-”= not reported. RCC = retrospective case-control study, PC = prospective cohort study, RC = retrospective cohort study.

International Pediatric Endosurgery Group annual congress from 2002 to 2013.

### 1.2. Inclusion and exclusion criteria

All included studies satisfied the following criteria: 1) comparing robot-assisted (RF) versus conventional laparoscopic fundoplication (LF), 2) involving pediatric patients with mean or median study group ages < 18 years, 3) reporting  $\geq 5$  patients in each study group, and 4) investigating either objective clinical outcome measures or GERD symptoms via standardized questionnaires. No language restrictions were imposed. In the event that duplication of data was observed, more recent studies or those with larger sample sizes were preferentially considered, with subsequent exclusion of earlier, smaller studies.

### 1.3. Outcomes of interest

Primary outcome measures of interest were intra-operative conversions, intra-operative complications, length of hospital stay (LOS), post-operative complications, operating time (OT), analgesia requirement and cost. Operating time was regarded as the ‘total’ time from first skin incision to skin closure. Secondary outcomes of interest were operative success, requirement for re-operation (i.e. due to wrap failure, post-operative symptoms related to surgery) and post-operative morbidity (defined as dysphagia, retching, belching). Operative success was regarded as improvement or resolution of GERD that was measured either objectively using upper gastrointestinal contrast studies, 24-hour pH monitoring studies, esophageal manometry, or esophagoscopy with or without biopsy; or subjectively using validated questionnaires such as the Pediatric GERD Symptom and Quality of Life Questionnaire [8,9].

### 1.4. Data extraction and synthesis

Two authors independently undertook literature searches, screened abstracts and assessed articles against eligibility criteria (TPC, HJM). Discrepancies were resolved by consensus and discussion with the senior author (AD). Corresponding authors were contacted regarding any missing data. The methodological quality of studies was appraised using a star-based modified Newcastle-Ottawa Scale (mNOS) that considers patient selection, inter-group comparability, and outcome assessment (maximum 3, 10, and 2 stars respectively; total/15) [10]. The 10 single-star variables used to grade comparability amongst study groups included age, weight, gender, indication for surgery, severity of GERD, major co-morbidities (including neurological impairment), proportion of re-do cases, proportion of cases involving concomitant procedures (i.e. gastrostomy), operative technique (including number of wrap sutures), and surgeon experience (or number of operating surgeons in each study group). Patient demographic and outcome data was extracted from included studies.

Statistical analysis was conducted using Review Manager® Version 5.1.7 for Windows (The Cochrane Collaboration, Software Update, Oxford, UK) and STATA v.11 statistical analysis software (StataCorp LP, TX, USA). A weighted random-effects model was used for all analyses. Studies were weighted based on sample size and quality of study scoring. Pooled odds ratios (OR) were calculated as the summary statistic for dichotomous variables and weighted mean difference (WMD) calculated for continuous variables. Both OR and WMD are reported with 95% confidence intervals (CI). A *P* value < 0.05 was considered statistically significant. Determination of heterogeneity was undertaken using the  $\chi^2$  test (Cochran’s *Q*) and *I*<sup>2</sup> value; with *I*<sup>2</sup>  $\geq 75\%$  denoting high degree of statistically significant heterogeneity. Risk of publication bias was assessed by visual inspection of funnel plots in addition to statistical estimation with both Begg and Mazumdar’s test and Egger’s test for small study effects.

## 2. Results

Six studies met inclusion criteria, involving 135 robot-assisted and 162 conventional laparoscopic fundoplication procedures (Tables 1–2) [11–16]. A summary of the results of our search strategy is shown in Fig. 1.

### 2.1. Study characteristics and appraisal of quality of evidence

No randomized controlled trials were identified. Four of the included studies were cohort studies and the remaining two studies were case-controlled studies (Table 1). All reported RF cases were undertaken using the da Vinci Surgical System® (Intuitive Surgical, CA). All included studies reported utilization of the Nissen fundoplication technique, with the exception of the study by Lehnert et al., that reported Thal fundoplications [14].

Only one included study was prospective in design, with patient allocation determined by parent preference following detailed explanation of both surgical techniques [14]. All other studies were retrospective and observational [11–13,15,16]; mostly with study group periods that were not synchronous and using historical LF controls [12,13,15]. All studies were single-institution in origin. No

**Table 2**

Distribution of patients with neurological impairment and also those requiring concomitant gastrostomy at the time of surgery.

	NI (%)			Gastrostomy (%)		
	RF	LF	<i>P</i> value	RF	LF	<i>P</i> value
Ivascu 2004 [16]	53%	53%	0.99	41%	46%	0.77
Lehnert 2006 [14]	0%	0%	n/a	0%	0%	n/a
Copeland 2008 [13]	-	-	-	34%	48%	0.34
Al-Bassam 2009 [11]	64%	72%	0.55	60%	64%	-
Anderberg 2009 [12]	79%	80%	-	-	-	-
Antao 2010 [15]	32%	45%	-	47%	58%	-

“-”= not reported. NI = neurologic impairment.

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