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Pediatric robotically assisted surgery for pyeloplasty and fundoplication

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VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Pediatric robotically assisted surgery for pyeloplasty and fundoplication

[Pediatrisk robotassisterad kirurgi för pyeloplastik och fundoplikation]

Running title: Pediatric robotically assisted surgery

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Abbreviations

GERD	Gastroesophageal reflux
RCT	Randomized controlled trial
UPJ	Ureteropelvic junction
UTI	Urinary tract infection

1. Summary of the Health Technology Assessment

Method and patient group

Robotically assisted surgery has been performed in the adult population since 1985, and the 'da Vinci' robot system was introduced in 2000. The experience from robotically assisted surgery in the pediatric population is limited, since pediatric patients are fewer than adult patients. Among the pediatric population, the most commonly studied surgical procedures are pyeloplasties and fundoplications.

Question at issue, PICO

Is robotically assisted surgery better for the patients than either conventional laparoscopy or open surgery, for pyeloplasty or fundoplication in pediatric patients?

PICO: (P=patients, I=intervention, C=comparison, O=outcome)

P: Children and youths <18 years in need of a pyeloplasty or fundoplication
I: Robotically assisted surgery (also called computer-assisted laparoscopic surgery)
C1: Laparoscopy
C2: Open surgical technique
O: *Critical (for decision making)*: resolution of hydronephrosis (pyeloplasty), symptom resolution (fundoplication)
Important (for decision making): postoperative pain, length of hospital stay, incision scar, need of reoperation, conversion to open surgery, time to own nutrition (fundoplication), relapse (fundoplication)
Less important (for decision making): operative time, anesthesia time, overall parental satisfaction
Complications, including functional problems with robot

Results

Thirty articles were identified, 15 cohort studies and 15 case series. Ten cohort studies and seven case series studied pyeloplasty, whereas five cohort studies and six case series studied fundoplication. Two of the case series studied both pyeloplasty and fundoplication.

Pyeloplasty - PICO 1: Robotically assisted surgery vs. laparoscopic surgery

It is uncertain whether robotically assisted surgery improves *resolution of hydronephrosis*, reduces *postoperative pain*, or shortens *operation time*, compared to laparoscopic surgery (GRADE ⊕○○○). It is uncertain whether *length of hospital stay*, and *complication* rates differ between robotically assisted surgery and laparoscopic surgery (GRADE ⊕○○○).
Incision scar, *need of reoperation*, *anesthesia time*, and *overall parental satisfaction* were not studied. *Conversion* to open or laparoscopic surgery - see PICO 2.

Fundoplication - PICO 1: Robotically assisted surgery vs. laparoscopic surgery

It is uncertain whether robotically assisted surgery reduces *postoperative pain* compared to laparoscopic surgery (GRADE ⊕○○○). It is uncertain whether *symptom resolution*, *need of reoperation*, *operative time*, *length of hospital stay*, or *complication* rates differ between robotically assisted surgery and laparoscopic surgery (GRADE ⊕○○○).
Incision scar, *time to own nutrition*, *relapse*, *anesthesia time*, and *overall parental satisfaction* were not studied. *Conversion* to open or laparoscopic surgery - see PICO 2

Pyeloplasty - PICO 2: Robotically assisted surgery vs. open surgery
It is uncertain whether robotically assisted surgery improves *resolution of hydronephrosis*, reduces *postoperative pain*, reduces the *length of hospital stay*, improves parental satisfaction regarding the *incision scar*, or prolongs the *operation time* compared to open surgery (GRADE ⊕○○○). It is uncertain whether *overall parental satisfaction*, or *complication* rates differ between robotically assisted surgery and open surgery (GRADE ⊕○○○). The *conversion* rates from robotically assisted surgery to open or laparoscopic surgery range from 0-12 % (GRADE ⊕○○○). *Need of reoperation,* and *anesthesia time* were not studied.

Fundoplication - PICO 2: Robotically assisted surgery vs. open surgery
It is uncertain whether robotically assisted surgery reduces *postoperative pain*, reduces the *length of hospital stay,* or prolongs the *operation time* compared to open surgery (GRADE ⊕○○○). It is uncertain whether *symptom resolution*, or *complication* rates differ between robotically assisted surgery and open surgery (GRADE ⊕○○○). It is uncertain whether the *conversion* rate to open surgery differs between robotically assisted surgery and open surgery. Very low quality of evidence (GRADE ⊕○○○).
Incision scar, need of reoperation, time to own nutrition, *relapse*, *anesthesia time,* and *overall parental satisfaction,* were not studied.

Ethical aspects
It may be ethically questionable to introduce a new expensive technique in routine health care when the quality of evidence for patient benefits and risks is very low.

Economical aspects
Laparoscopic and robotically assisted surgeries seem to be more time consuming than open surgery (cost increasing). There seems to be a tendency towards shorter hospitalisations with robotically assisted surgery compared to open surgery (cost reducing). The cost of a 'da Vinci' robot single console is approximately 1.7 million EUR, and the service program costs 150,000 EUR/year, from the second year onwards. A required training simulator costs 65,000 EUR. The estimated additional cost per operation with robotically assisted surgery, compared to open surgery is approx. 9,600 EUR during year one, and approx. 3,100 EUR during year five.

Concluding remarks
The procedures pyeloplasty and fundoplication in pediatric surgery can be performed with robotically assisted surgery, conventional laparoscopy, or open surgery. There is no documentation suggesting that any of these techniques is superior to another, regarding the outcomes studied in this report. All the identified studies were cohort studies contributing to very low quality of evidence (GRADE ⊕○○○). It may be unethical to introduce a new expensive technique in routine health care, when the quality of evidence for patient benefits and risks is very low.

2. Swedish Summary of the Health Technology Assessment

Metod och patientgrupp

Robotassisterad kirurgi har utförts bland vuxna sedan år 1985, och med det moderna 'da Vinci' robotkirurgisystemet sedan år 2000. Erfarenheter från robotassisterad kirurgi inom pediatrik är begränsade, eftersom antalet opererade barn är lägre än antalet vuxna. De vanligaste och mest studerade ingreppen som utförts på barn är pyeloplastik och fundoplikation.

Fokuserad fråga, PICO

Är robotassisterad kirurgi bättre, avseende patientnytta, än konventionell laparoskopi, eller öppen kirurgi vid pyeloplastik eller fundoplikation på barn?

PICO: (P=patients, I=intervention, C=comparison, O=outcome)
P: Barn och ungdomar <18 år i behov av pyeloplastik eller fundoplikation
I: Robotassisterad kirurgi
C1: Laparoskopi
C2: Öppen kirurgi

O: Resolution av hydronefros (pyeloplastik), symtomresolution (fundoplication), postoperativ smärta, vårdtid på sjukhus, ärrproblematik, behov av reoperation, konvertering till öppen/laparoskopisk kirurgi, tid till egen nutrition (fundoplikation), recidiv (fundoplikation), komplikationer (inkl. funktionsfel hos roboten), operationstid, narkostid, föräldranöjdhet (övergripande)

Studerad patientnytta och risker

Trettio artiklar; 15 kohort studier och 15 fallserier inkluderades. Tio kohortstudier, och sju fallserier studerade pyeloplastik. Fem kohortstudier och sex fallserier studerade fundoplikation. Två av fallserierna studerade både pyeloplastik och fundoplikation.

PICO 1: Pyeloplastik - Robotassisterad kirurgi jämfört med laparoskopisk kirurgi
Det är osäkert huruvida robotassisterad kirurgi förbättrar *resolution av hydronefros,* minskar *postoperativ smärta*, eller förkortar *operationstiden*, jämfört med laparoskopisk kirurgi. Det vetenskapliga underlaget är otillräckligt (GRADE ⊕○○○). Det är osäkert huruvida *vårdtid på sjukhus,* eller förekomst av *komplikationer* skiljer sig mellan robotassisterad kirurgi och laparoskopisk kirurgi. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○).
Inga studier hade utfallsmåtten *ärrproblematik, behov av reoperation, narkostid* eller *föräldranöjdhet*. *Konvertering* till öppen eller laparoskopisk kirurgi, se PICO 2.

PICO 1: Fundoplikation - Robotassisterad kirurgi jämfört med laparoskopisk kirurgi
Det är osäkert huruvida robotassisterad kirurgi minskar *postoperativ smärta* jämfört med laparoskopisk kirurgi. Det vetenskapliga underlaget är otillräckligt (GRADE ⊕○○○).
Det är osäkert huruvida *symtomresolution, behov av reoperation, operationstid, vårdtid på sjukhus,* eller förekomsten av *komplikationer* skiljer sig mellan robotassisterad kirurgi och laparoskopisk kirurgi. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○).
Inga studier hade utfallen *ärrproblematik, tid till egen nutrition, recidiv, narkostid,* eller *föräldranöjdhet. Konvertering* till öppen eller laparoskopisk kirurgi - se PICO 2.

PICO 2: Pyeloplastik - Robotassisterad kirurgi jämfört med öppen kirurgi
Det är osäkert huruvida robotassisterad kirurgi förbättrar *resolution av hydronefros*, minskar *postoperativ smärta*, förkortar *vårdtid på sjukhus*, ökar föräldranöjdheten avseende *ärrproblematik*, eller förlänger *operationstiden*, jämfört med öppen kirurgi. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○). Det är osäkert huruvida *föräldranöjdhet (övergripande)*, eller förekomsten av *komplikationer*, skiljer sig mellan robotassisterad kirurgi och öppen kirurgi. Det vetenskapliga underlaget är otillräckligt (GRADE ⊕○○○). *Konverteringsgraden* från robotassisterad kirurgi till öppen eller laparoskopisk kirurgi varierar mellan 0-12% i studierna. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○).
Utfallen *behov av reoperation*, samt *narkostid* rapporterades inte i studierna.

PICO 2: Fundoplikation - Robotassisterad kirurgi jämfört med öppen kirurgi
Det är osäkert huruvida robotassisterad kirurgi minskar *postoperativ smärta*, minskar *vårdtid på sjukhus*, eller förlänger *operationstiden*, jämfört med öppen kirurgi. Det vetenskapliga underlaget är otillräckligt (GRADE ⊕○○○). Det är osäkert huruvida *symtomresolution*, eller förekomsten av *komplikationer* skiljer sig mellan robotassisterad kirurgi och öppen kirurgi. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○). Det är osäkert huruvida *konversionsgraden* till öppen kirurgi skiljer sig åt mellan robotassisterad och laparoskopisk kirurgi. Otillräckligt vetenskapligt underlag (GRADE ⊕○○○).
Utfallen *ärrproblematik, behov av reoperation, tid till egen nutrition, narkostid, recidiv,* samt *föräldranöjdhet*, rapporterades inte i studierna.

Etiska aspekter
Det kan ifrågasättas huruvida det är etiskt försvarbart att introducera en ny kostsam teknologi i rutinverksamhet, då det vetenskapliga underlaget avseende patientnytta och risker är otillräckligt.

Ekonomiska aspekter
Konventionell laparoskopisk kirurgi och robotassisterad kirurgi tenderar att vara mer tidskrävande än öppen kirurgi (kostnadsdrivande). Det finns en tendens mot kortare vårdtid med robotassisterad kirurgi vid jämförelse mot öppen kirurgi (kostnadsbesparande). Inköpskostnaden för en 'da Vinci' robot är ca 1,7 miljoner EUR. Serviceprogram, från år två och framåt, tillkommer med en årlig kostnad av 150 000 EUR. En träningssimulator kostar 65 000 EUR. Jämfört med öppen kirurgi uppskattas kostnadsökningen med robotassisterad kirurgi till ca 9 600 EUR per operation under det första året, och till ca 3 100 EUR per operation under det femte året.

Sammanfattande slutsats
Ingreppen pyeloplastik och fundoplikation inom barnkirurgi kan utföras med robotassisterad kirurgi, konventionell laparoskopi, eller öppen kirurgi. Det finns ingen dokumentation som styrker att någon av dessa metoder är att föredra före de andra. Det vetenskapliga underlaget består av kohortstudier som sammantaget resulterar i ett otillräckligt vetenskapligt underlag (GRADE ⊕○○○). Det kan vara oetiskt att införa en ny kostsam teknologi i rutinverksamhet där det vetenskapliga underlaget är otillräckligt avseende patientnytta och risker.

Projekttid:

Projektet har pågått under perioden 2013-05-07–2014-02-26.
Sista uppdatering av artikelsökning maj 2013

Utlåtande och sammanfattande bedömning från HTA-Kvalitetssäkringsgrupp (1 & 2)

HTA-kvalitetssäkringsgruppen har ett uppdrag att yttra sig över genomförda HTA i Västra Götalandsregionen. Yttrandet skall innefatta sammanfattning av frågeställning, samlat kunskapsläge och evidensgradering för patientnytta och risker samt ekonomiska och etiska aspekter för den studerande teknologin.

För HTA-kvalitetssäkringsgruppen 2014-02-26

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3. Participants in the project

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Conflicts of interest for the proposer or the participants in the work group

No.

4. The assessed health technology or method

Diseases/disorders of interest and their degree of severity

Pyeloplasty is a surgical procedure used in children with ureteropelvic junction (UPJ) obstruction, due to a malformation with stenosis of the UPJ, or a crossing vessel to the lower renal pole. Only approximately 25% of the patients with UPJ obstruction require surgery. A significant obstruction can cause renal deterioration, urinary tract infection, stone formation and pain. UPJ obstruction is diagnosed prenatally or due to symptoms. Indications for surgery are severe, or increasing dilatation of the renal pelvis seen on renal ultrasound, less than 40% relative renal function or loss of more than 10% split function on serial renal isotope scans, recurrent urinary tract infections, stone formation in a dilated renal pelvis and/or flank pain.

☐ Risk of premature death
☑ Risk of permanent illness or damage, or reduced quality of life
☐ Risk of disability and health-related quality of life

Fundoplication is recommended for children who have complications or persistent symptoms related to gastroesophageal reflux (GERD) that are not improved by medication. Symptoms of gastroesophageal reflux include vomiting, esophagitis (heart burn) gastroesophageal stricture, recurrent pneumonia, breathing problems, and inadequate growth. Before surgery is performed the child may have one or more tests confirming GERD, such as a pH probe study or esophagram.

☐ Risk of premature death
☑ Risk of permanent illness or damage, or reduced quality of life
☐ Risk of disability and health-related quality of life

Prevalence and incidence of the disease/disorder

The incidence of prenatal renal dilatation is reported to be 1-1.4% (Baskin and Kogan, 2005). Most hydronephrosis cases resolve spontaneously after birth and leaves only 0.2-0.4% of the affected children with significant urinary tract disease. Two-thirds of the cases of prenatal urinary tract dilatation is due to UPJ obstruction.
Another group of patients with UPJ obstruction, presents later with symptoms as flank pain, stone formation or urinary tract infection.
At Queen Silvia Children's Hospital 12-15 pyeloplasties are performed every year. A younger group with mainly antenatally detected hydronephrosis is operated at a median age of 0.8 years and comprises approximately 30% of the patients operated with pyeloplasty. The remaining 70%, presenting with symptoms, are operated at a median age of 8.3 years.

The prevalence of GERD varies by age. In a study of parent reporting and symptom scores, 67% of healthy infants aged four months had GERD, and the prevalence decreased to 21% by age seven months (Nelson *et al*., 1997). A one-year follow-up study by the same author demonstrated that vomiting spontaneously resolved in nearly all of these cases (Nelson *et al*., 1998). An estimated 85% of premature infants have GERD, and a vast majority of the cases resolve without treatment. Children with neurological disorders also have an increased prevalence of GERD. In one referral centre, the rate of GERD was higher in patients older than one year with neurological impairment, than in healthy children (69% vs 47%) (Halpern *et al*., 1991). Another study found that 65% of patients who underwent anti reflux surgery were neurologically impaired (Pearl *et al*., 1990). At Queen Silvia Children's Hospital, about 25 patients per year are treated with fundoplication because of GERD that impairs their lives severely.

Present treatment of the disease/disorder

UPJ obstruction is surgically treated with open or laparoscopic pyeloplasty. In Sweden, pyeloplasties in children are centralised to four university hospitals. At these centres, children with a weight of more than 15 kg undergo surgery with laparoscopic technique. Until today, only Skåne University Hospital in Lund use robotic assisted surgery. Irrespective of whether open, laparoscopic, or robotic assisted surgery is used, pyeloplasties are carried out in the same way, except from the access. In Sweden, open pyeloplasty is always performed retroperitoneally, while laparoscopic pyeloplasty is performed transabdominally. There are only a few centres in the world performing laparoscopic pyeloplasty retroperitoneally, since this is technically demanding due to narrow space. Length of hospital stay is approximately one to three days after surgery, with no difference between open and laparoscopic surgery.

The goal of a fundoplication is to prevent stomach contents from returning to the oesophagus. This operation is accomplished by wrapping the upper portion of the stomach around the lower portion of the oesophagus, tightening the outlet of the oesophagus as it empties into the stomach. After a fundoplication, food and fluids can pass into the stomach but are prevented from returning to the oesophagus, causing symptoms of oesophageal reflux. A large skin incision may not be required, since in most cases, a pediatric surgeon can perform a fundoplication using laparoscopic instruments placed through three to four band-aid sized incisions on the abdomen. Length of hospital stay is approximately 3-10 days, depending on comorbidity.

Number of patients per year that undergo current treatment regimen

From year 2009 to 2013, 70 pyeloplasties were performed (approximately 14/year) at Queen Silvia Children´s hospital. During the last two years this includes seven patients with laparoscopic pyeloplasties.

The number of children that undergo fundoplication is increasing. Ten years ago 11 fundoplication operations were performed every year, whereas nowadays about 20 operations are done annually. Most operations are now performed with laparoscopic technique, with only a few open surgeries.

During the past five years, 92 operations with fundoplication where performed at Queen Silvia Children’s Hospital: 81 with laparoscopic technique and 11 open surgeries.

The normal pathway of a patient through the health care system

Hydronephrosis due to UPJ obstruction is diagnosed prenatally in 30% of the cases. If a routine ultrasound in the 18^{th} week of gestation shows renal dilatation the child is followed postnatally with repeated renal ultrasounds and MAG-3 renograms. The same investigations are performed if the child presents with urinary tract infection or flank pain due to a hydronephrosis and UPJ obstruction.

The patients are referred to the pediatric surgery clinic after investigations for symptoms of severe GERD. Neurologically impaired children are often referred from the pediatricians or the pediatric neurologists**.**

Actual wait time in days for medical assessment/treatment

The waiting time at Queen Silvia Children’s hospital for pyeloplasty or fundoplication is maximum for six months. Maximum wait to a visit at the policlinic is three months and then another three months to undergo surgery. In the case of pyeloplasty the wait time is shorter if the kidney function is threatened.

5. Present Health Technology

Name/description of the health technology at issue

Most surgical procedures are accomplished in the same manner regardless if the access to the operated area is achieved through open, laparoscopic, or robotic assisted surgery. In robotic assisted surgery the robot is holding the instruments instead of the surgeon. The instruments belonging to the robot are more precise and have the ability to rotate 360 degrees. It is not possible to feel tension with the robotic instruments.

Why the current HTA-analysis was initiated

Development of robotically assisted surgery has led to introduction of the technology for numerous surgical procedures, in general without supporting data from high quality clinical trials, on patient benefits or risks. This is also the case in pediatric surgery.

Among the surgeons a major advantage with robotically assisted surgery is considered to be the ergonomic improvements, since most of the work can be done in a console, instead of working with elevated arms and shoulders.

Despite the possible ergonomic benefits, the current HTA-analysis focuses on patient benefits (and risks) of the two most studied pediatric surgical procedures with robotically assisted surgery (i.e. fundoplication and pyeloplasty). Numerous other pediatric surgical procedures have been suggested suitable for robotically assisted surgery, but these have been studied to a lesser extent.

The central question for the current HTA project in one sentence

Is robotically assisted surgery better for the patients than conventional laparoscopy, or open surgery for pyeloplasty or fundoplication in pediatric patients?

PICO: P= Patients, I= Intervention, C= Comparison, O=Outcome

P: Children and youths <18 years in need of a pyeloplasty or fundoplication
I: Robotically assisted surgery (also called computer-assisted laparoscopic surgery)
C1: Laparoscopy
C2: Open surgical technique

O= *Critical (for decision making)*
Resolution of hydronephrosis (pyeloplasty)
Symptom resolution (fundoplication)

Important (for decision making)
Postoperative pain
Length of hospital stay
Incision scar
Need of reoperation
Conversion to open surgery
Time to own nutrition (fundoplication)
Relapse (fundoplication)
Complications, including functional problems with robot

Less important (for decision making)
Operative time
Anesthesia time
Overall parental satisfaction

6. Review of Quality of Evidence

Search strategy, study selection and references (Appendix 1)

During May 2013 two librarians (E-LD, ME) performed systematic searches in PubMed, Embase, the Cochrane Library, and a number of HTA-databases. Reference lists of relevant articles were also scrutinized for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in Appendix 1. The librarians conducted the literature searches, selected studies and independently assessed the obtained abstracts and a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to the work group, who read the articles independently and then decided in a consensus meeting which articles that should be included.

The literature search identified a total of 463 articles (after removal of duplicates). The librarians then excluded 404 articles after reading their abstracts. Another 19 articles were excluded by the librarians after reading the articles in full text. The remaining 39 articles were sent to the project group, and 30 of them were finally included in the report. Fifteen of the articles were cohort studies that have been critically appraised using checklists from SBU (Swedish Council on Health Technology Assessment) for cohort studies. The remaining 15 articles were case series.

Included studies – design and patient characteristics (Appendix 2)
Excluded articles – (Appendix 3)
Outcome tables – (Appendix 4)
Summary of Findings, SoF-table, (Appendix 5)

Ongoing research

A search in Clinicaltrials.gov 2013-09-17 using the search terms (Robotic OR Robotics OR DaVinci OR Zeus OR Telerobotic OR Telerobotics) AND (Child OR Children OR Pediatric OR Pediatrics OR Adolescent OR Adolescents OR Infant OR Infants OR Neonates) AND (Fundoplication OR Nissen OR Pyeloplasty) identified one trial. The trial is a prospective cohort, on children who receive a robotic pyeloplasty procedure at Connecticut Children's Medical Center, estimated to be completed in March 2014.
In addition, one cohort study with historical controls, 'in press', was identified (Bansal *et* al., 2013). This study was the first to compare robotically assisted surgery with open surgery in infants (n=70), under one year of age. Only nine individuals were operated with robotically assisted surgery. The study showed significantly shorter postoperative pain, shorter length of hospital stay, and shorter operative time with robotically assisted surgery, but the operative time was not quite comparable since a lot of other details differed during the procedures. The complication rate was higher, 33% (n=3: one urinary leakage from anastomosis, one ileus, one UTI) in the robotically assisted surgery group, than in the open surgery group 7% (n=4).

Medical societies or health authorities that recommend the new health technology

To our knowledge, there are no recommendations concerning robotically assisted surgery. The National Board of Health and Welfare has made a report about the expansion of robotically assisted surgery but they have not taken position on the issue.

- ☐ **The National Board of Health and Welfare**
- ☐ **Medical societies**
- ☐ **Other health authority**

Present knowledge of the health technology

Thirty articles were identified (Appendix 2:1, 2:2), 15 cohort studies and 15 case series. Ten cohort studies and seven case-series studied pyeloplasty, whereas five cohort studies and six case series studied fundoplication. Two of the case series studied both pyeloplasty and fundoplication.

PICO 1: Pyeloplasty - Robotically assisted surgery vs. laparoscopic surgery

Resolution of hydronephrosis (Appendix 4:1)

Three cohort studies reported resolution of hydronephrosis comparing robotically assisted surgery (85-94%) and laparoscopic surgery (95-100%) in pyeloplasty. There were no significant differences between the study groups.
Conclusion: It is uncertain whether robotically assisted surgery improves resolution of hydronephrosis compared to laparoscopic surgery.
Very low quality of evidence (GRADE ⊕○○○).

Postoperative pain (Appendix 4:2)
Two cohort studies compared postoperative pain between robotically assisted surgery and laparoscopic surgery. One study reported significantly less use of one analgesic drug (Ketorolac), but all other pain related outcomes were not significantly different between the study groups. In the other study all patients were reported as pain free postoperatively, in both study groups.
Conclusion: It is uncertain whether robotically assisted surgery reduces postoperative pain compared to laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Length of hospital stay (Appendix 4:3)
Three cohort studies compared the length of hospital stay after robotically assisted surgery (1-6 days) and laparoscopic surgery (1-7 days). There were no significant differences between the study groups.
Conclusion: It is uncertain whether length of hospital stay differs after robotically assisted surgery or laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Incision scar (Appendix 4:4)
The outcome was not studied for PICO 1.

Need of reoperation
The outcome was not studied.

Conversion to open or laparoscopic surgery - see PICO 2 (Appendix 4:5)

Operative time (Appendix 4:6)
Four cohort studies compared the operative times between robotically assisted surgery and laparoscopic surgery. Three out of four studies showed significantly shorter operative time for robotically assisted surgery compared to laparoscopic surgery. The smallest study did not detect any significant difference between the study groups. The differences between groups in all four studies ranged between 14-89 min. The stent placement strategies differed between the groups in two of the studies.
Conclusion: It is uncertain whether operation time is shorter for robotically assisted surgery compared to laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Anesthesia time
The outcome was not studied.

Overall parental satisfaction (Appendix 4:7)
The outcome was not studied for PICO 1 -pyeloplasty.

Complications (Appendix 4:8)
Four cohort studies compared complication rates for pyeloplasty with robotically assisted surgery and laparoscopic surgery, with no significant differences between the study groups. The complication rates in the cohort studies were 0-11% for robotically assisted surgery, and 0-15% for laparoscopic surgery, but the classification of complications differed between the studies.
In nine cases series, the complication rates, for robotically assisted surgery for pyeloplasty ranged from 0% to 29%.
Conclusion: It is uncertain whether the complication rates differ between robotically assisted surgery and laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Fundoplication - PICO 1: Robotically assisted surgery vs. laparoscopic surgery

Symptom resolution (Appendix 4:9)

Four cohort studies reported postoperative symptom resolution. All studies reported improvement of preoperative symptoms, without significant differences in resolution rates between robotically assisted surgery (70-100%) and laparoscopic surgery (60-100%).
Conclusion: It is uncertain whether symptom resolution differs between robotically assisted surgery and laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Postoperative pain (Appendix 4:10)

Three cohort studies compared postoperative pain after fundoplication with robotically assisted surgery and laparoscopic surgery. All three studies showed almost similar use of postoperative analgesics.
Conclusion: It is uncertain whether robotically assisted surgery reduces postoperative pain compared to laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Length of hospital stay (Appendix 4:11)
Four cohort studies compared the length of hospital stay between robotically assisted surgery (2.9-4.6 days) and laparoscopic surgery (3.5-5.2 days). The results were inconsistent across the studies.
Conclusion: If is uncertain whether length of hospital stay differs between robotically assisted surgery and laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Incision scar
The outcome was not studied.

Need of reoperation (Appendix 4:12)
Need of reoperation after fundoplication was studied in three cohort studies. In two of the studies there were no reoperations in the study groups. The third study reported reoperations as 'most common complications' in the robotically assisted surgery group (8%) and in the laparoscopic surgery group (6%), thus it is unclear if all reoperations were reported.
Conclusion: It is uncertain whether the need of reoperation differs between robotically assisted surgery and laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Conversion to open or laparoscopic surgery - see PICO 2 (Appendix 4:13)

Time to own nutrition
The outcome was not studied.

Relapse
The outcome was not studied.

Operative time (Appendix 4:14)
Five cohort studies compared the operative times between robotically assisted surgery and laparoscopic surgery. All studies reported largely similar operative times for robotically assisted surgery (127-213 min) and laparoscopic surgery (107-207 min). The results were inconsistent across the studies.
Conclusion: It is uncertain whether the operation time differs between robotically assisted surgery and laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Anesthesia time
The outcome was not studied.

Overall parental satisfaction
The outcome was not studied.

Complications (Appendix 4:15)
Four cohort studies compared complication rates between fundoplications with robotically assisted surgery and laparoscopic surgery, with no significant differences between the study groups. The complication rates in the cohort studies were 0-14% for robotically assisted surgery, and 0-16% for laparoscopic surgery.
In eight cases series, the complication rates for robotically assisted surgery for fundoplication ranged from 0% to 47%, but the classification of complications differed between the studies.
Conclusion: It is uncertain whether the complication rates differ between robotically assisted surgery and laparoscopic surgery. Very low quality of evidence (GRADE ⊕○○○).

Pyeloplasty - PICO 2: Robotically assisted surgery vs. open surgery

Resolution of hydronephrosis (Appendix 4:1)

Four cohort studies reported resolution of hydronephrosis after robotically assisted surgery (77-100%) and open surgery (68-97%) for pyeloplasty. There were no significant differences between the study groups.
Conclusion: It is uncertain whether robotically assisted surgery improves resolution of hydronephrosis compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Postoperative pain (Appendix 4:2)
Four cohort studies reported postoperative pain after robotically assisted surgery versus open surgery. One study reported significantly less postoperative pain in the robotically assisted surgery group, measured by use of morphine postoperatively, whereas three studies did not report any significant differences between the study groups.
Conclusion: It is uncertain whether robotically assisted surgery reduces postoperative pain compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Length of hospital stay (Appendix 4:3)
Five cohort studies reported length of hospital stay for robotically assisted surgery (1.6-2.4 days) compared to open surgery (2.6-4.0 days). Three of the studies reported significantly shorter length of hospital stay for robotically assisted surgery, and two studies did not report significant differences between the groups.
Conclusion: It is uncertain whether robotically assisted surgery reduces the length of hospital stay compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Incision scar (Appendix 4:4)
One cohort study reported parental satisfaction concerning incision scar after robotically assisted surgery (median score: 5) compared to open surgery (median score: 4). The difference in satisfaction scores was significant, in favour of robotically assisted surgery. The response rate to the questionnaire was 58% and 42%, for the robotically assisted surgery and open surgery groups, respectively.
Conclusion: It is uncertain whether robotically assisted surgery improves parental satisfaction regarding the incision scar compared to open surgery.
Very low quality of evidence (GRADE ⊕○○○).

Need of reoperation
The outcome was not studied.

Conversion to open or laparoscopic surgery (Appendix 4:5)
Six cohort studies reported conversion rates from robotically assisted surgery to laparoscopic surgery or to open surgery. One study reported three (9%) conversions to laparoscopy from robotically assisted surgery due to technical problems with the robot. Another study reported two (12%) conversions from robotically assisted surgery to open surgery, whereas five studies reported no conversions to open surgery.
Conclusion: The conversion rates from robotically assisted surgery to open or laparoscopic surgery range from 0-12 %. Very low quality of evidence (GRADE ⊕○○○).

Operative time (Appendix 4:6)
Four cohort studies compared the operative times between robotically assisted surgery and open surgery. All four studies showed significantly longer operative times for robotically assisted surgery compared to open surgery, with between group differences from 38 min to 115 min. In two of the studies, where more urethral stents and cystoscopies were seen in the robotically assisted surgery group, the between group differences were from 38 min to 90 min.
Conclusion: It is uncertain to what extent robotically assisted surgery prolongs the operation time compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Anesthesia time
The outcome was not studied.

Overall parental satisfaction (Appendix 4:7)
One cohort study comparing overall parental satisfaction with robotically assisted surgery versus open surgery showed no significant difference between the study groups (both median score: 5).
Conclusion: It is uncertain whether overall parental satisfaction differs between robotically assisted surgery and open surgery. Very low quality of evidence (GRADE ⊕○○○).

Complications (Appendix 4:8)
Four cohort studies compared complication rates between robotically assisted surgery for pyeloplasty and open pyeloplasty surgery, with no significant differences between the study groups. The complication rates in the cohort studies were 1.7-15% for robotically assisted surgery, and 0-12.5% for open surgery, but the classification of complications differed between the studies. Cases series for robotically assisted surgery are reported under PICO 1 - pyeloplasty.
Conclusion: It is uncertain whether the complication rates differ between robotically assisted surgery and open surgery. Very low quality of evidence (GRADE ⊕○○○).

Fundoplication - PICO 2: Robotically assisted surgery vs. open surgery

Symptom resolution (Appendix 4:9)

Two cohort studies reported symptom resolution after robotically assisted surgery (70-100%) and open surgery (88-100%), with no significant differences between the study groups.
In one of the studies a tendency towards improved symptom resolution was seen in the robotically assisted surgery group, compared to open surgery.
Conclusion: It is uncertain whether symptom resolution differs between robotically assisted surgery and open surgery. Very low quality of evidence (GRADE ⊕○○○).

Postoperative pain (Appendix 4:10)
Two cohort studies compared postoperative pain after fundoplication with robotically assisted surgery and open surgery. Both studies reported significantly less days when morphine was required after robotically assisted surgery compared to open surgery, with a mean difference between groups of 2.2, and 2.4 days, respectively.
Conclusion: It is uncertain whether robotically assisted surgery reduces postoperative pain compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Length of hospital stay (Appendix 4:11)
Three cohort studies reported length of hospital stay, with significantly shorter stay after robotically assisted surgery (2.9-4 days) compared to open surgery (3.5-7-9 days). The mean differences between groups ranged from 0.6-4.1 hospital days, with the largest study showing the smallest difference.
Conclusion: It is uncertain whether robotically assisted surgery reduces the length of hospital stay compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Incision scar
The outcome was not studied.

Need of reoperation
The outcome was not studied.

Conversion to open or laparoscopic surgery (Appendix 4:13)
Five cohort studies reported conversion rates from robotically assisted surgery or laparoscopic surgery to open surgery, with no significant differences between the study groups. The largest study (n=100) reported 4% conversions in the robotically assisted surgery group, and 2% in the laparoscopic surgery group.
Conclusion: It is uncertain whether the conversion rate to open surgery differs between robotically assisted surgery and laparoscopic surgery.
Very low quality of evidence (GRADE ⊕○○○).

Time to own nutrition
The outcome was not studied.

Relapse
The outcome was not studied.

Operative time (Appendix 4:14)
Three cohort studies compared the operative times between robotically assisted surgery (145-160 min) and open surgery (73-215 min), with significantly longer operative times for robotically assisted surgery. The mean differences between the study groups were 78-92 min, across the studies.
Conclusion: It is uncertain to what extent robotically assisted surgery prolongs the operation time compared to open surgery. Very low quality of evidence (GRADE ⊕○○○).

Anesthesia time
The outcome was not studied.

Overall parental satisfaction
The outcome was not studied.

Complications (Appendix 4:15)
Three cohort studies compared complication rates between robotically assisted surgery for fundoplication surgery and open surgery, with no significant differences between the study groups. The complication rates in the cohort studies were 0-14% for robotically assisted surgery, versus 0-10% for open surgery. Cases series for robotically assisted surgery are reported under PICO 1 - fundoplication.
Conclusion: It is uncertain whether the complication rates differ between robotically assisted surgery and open surgery. Very low quality of evidence (GRADE ⊕○○○).

7. Ethical aspects

Ethical consequences

It may be ethically questionable to introduce a new expensive technology with very low quality of evidence for patient benefits and risks.
There are obvious displacement risks if economic resources are redirected to a recently prioritised and highly selected patient group.

8. Organisation

When can the new health technology be put into practice

We expect to introduce robotically assisted surgery in well-informed patients (parents) during 2014. Before introduction, the surgical team will need training for a period of approximately three months. The education will thereafter continue in parallel with the introduction of the technology.

Use of this technology used in other hospitals in Region Västra Götaland of Sweden

In Region Västra Götaland there is presently one robot at the Sahlgrenska University Hospital and one additional robot is planned for the surrounding areas. There is also a robot at Varberg Hospital, in the neighbouring Region Halland.

Consequences of the new health technology for personnel, according to the work group

The robotically assisted surgery team includes two surgical nurses, two assistant nurses, two consultants and two fellow surgeons. With the introduction of robotically assisted surgery there will be an educational need for the surgical team. The education will partly need to be done in Paris or Strasbourg with hands-on training, in a two-day session. Thereafter training in the simulator will be necessary, preferably with our own robot. For the hospital this leads to a loss of working capacity during the education.

Consequences for other clinics or supporting functions at the hospital or in the whole Region Västra Götaland of Sweden

When the robotically assisted surgery is introduced, we predict that it will be used in approximately 250 pediatric surgical procedures/year (when the Pediatric surgery in Sweden will be centralised, the numbers may double).
The Pediatric Surgery Department in Lund has since several years a well-established robotically assisted surgery team, and the Pediatric Surgical Department in Uppsala started up in autumn 2013.

9. Economy aspects

Present costs of currently used technologies

The total mean cost for an open pyeloplasty at our hospital today is approximately 70,000 SEK (approx. 8,100 EUR). Corresponding cost for the laparoscopic procedure is approximately 98,000 SEK (approx. 11,300 EUR). The main reason for the higher cost in the laparoscopic group is longer operative time. The total mean cost for a laparoscopic fundoplication is approximately 130,000 SEK (approx. 15,000 EUR), with a median cost of 117,000 SEK (approx. 13,500 EUR).

Expected costs of the new health technology

The cost increase will mainly consist of the purchase cost of the robot, and its annual service (Table 1). The educational cost for the team will be included in the price of the robot, except for the loss of production cost of the robotically assisted surgery team during the education. A 'da Vinci' robot single console cost approximately 1.7 million EUR. A skills simulator that costs 65,000 EUR will be needed, and a service program for the robot, which costs 150,000 EUR each year from the second year onwards. The instruments, draping, etc. cost between 1,200-1,500 EUR, depending of the procedure.

Table 1. Additional cost of robotic assisted surgery (EUR) compared to open surgery, based on an estimated number of operations for year 1 and year 5

Year	Operations	Instruments	Robot[2]	Service program	Total cost	Cost per operation
1	30	45,000	242,857	0	287,857	9,595
5	250	375,000	242,857	150,000	767,857	3,071

[1] The cost of instruments for open surgery was considered negligible.
[2] Depreciation time: 7 years, and the cost of a skills simulator (65,000 EUR) not included.

If the cost of robotically assisted surgery is to be compared with laparoscopic surgery, the cost of instruments for conventional laparoscopic surgery need to be deducted with 1,000-1,100 EUR per operation.

Total change of cost

The total change of cost is mainly an investment cost of the new devices. However, it is uncertain to what extent robotically assisted surgery influences the operation time compared to open surgery. It is our impression that both laparoscopic and robotically assisted surgery are more time consuming than open surgery, which would probably increase the costs. It is also uncertain whether the length of hospital stay differs between robotically assisted surgery and laparoscopic surgery, or open surgery (8,281 SEK [approx. 960 EUR]/24 hours at the ward). There seems to be a tendency towards shorter hospitalisations with robotically assisted surgery compared to open surgery, which in turn would lower the costs.

Possibility to adopt and use the technology within the present clinic/hospital budget

No. The purchase of the robot, education, and need of relocation has not been accounted for in the current budget.

Available analyses of health economy

One health economical study (Anderberg, 2009) was identified which concludes that robotically assisted surgery for fundoplication has a 7% higher cost compared to conventional laparoscopic surgery, and 9% lower cost than open fundoplication. The introduction of robotically assisted surgery into surgical practice involves increased hospital costs, mainly because of the cost of investment in new instruments.

10.Unanswered questions

Important gaps in scientific knowledge

There is an absence of high-quality controlled trials on robotically assisted surgery conducted in pediatric settings. Robotically assisted surgery has been introduced in pediatrics, without confirming results demonstrating patient benefit.

Interest to start studies/trials within the research field

When introducing the new technique we wish to coordinate a national randomized controlled trial on robotically assisted surgery in pediatric surgery.

Appendix 1, Search strategy, study selection and references

Question(s) at issue:
Is robot-assisted laparoscopy better for the patients than conventional laparoscopy, or open surgery for pyeloplasty or fundoplication in pediatric patients?

PICO: *(P=Patient I=Intervention C=Comparison O=Outcome)*

P: Children and youths <18 years in need of a pyeloplasty or fundoplication
I: Robot-assisted surgery (also called computer-assisted laparoscopic surgery)
C1: Laparoscopy
C2: Open surgical technique
O: *Critical (for decision making)*
Resolution of hydronephrosis (pyeloplasty)
Symptom resolution (fundoplication)

Important (for decision making)
Postoperative pain
Length of hospital stay
Incision scar
Need of reoperation
Conversion to open surgery
Time to own nutrition (fundoplication)
Relapse (fundoplication)
Complications, including functional problems with robot

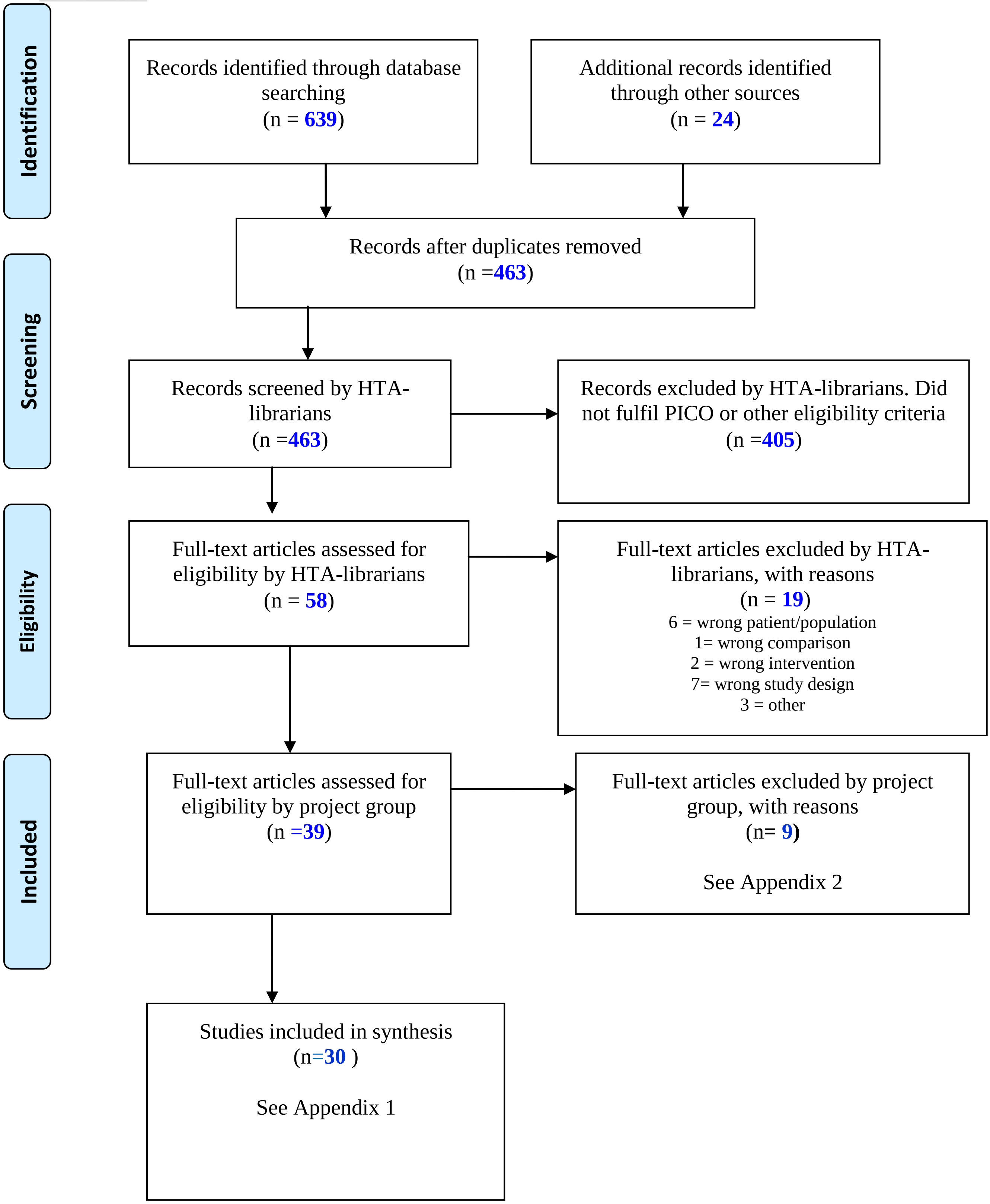
Less important (for decision making)
Operative time
Anesthesia time
Overall parental satisfaction

Limits
- Human
- Not older robotic systems e.g. AESOP

Eligibility criteria
Studydesign*:*
Randomized controlled trials
Systematic reviews
Non-randomized controlled studies
No case reports or review articles
Case series etc. if ≥ 10 (for complications)

Publication date: 2000-
Language:
Danish, English, Norwegian, Swedish, Icelandic

Selection process – flow diagram



Search strategies

Database: PubMed
Date: 2013-05-20
No of results: 208

Search	Query	Items found
#26	**Search (#24) NOT #25**	**208**
#25	Search (Editorial[ptyp] OR Letter[ptyp] OR Comment[ptyp])	1238174
#24	Search ((#1) AND #2) AND #16 Filters: Publication date from 2000/01/01; Danish; English; Icelandic; Norwegian; Swedish	211
#17	Search ((#1) AND #2) AND #16	236
#16	Search Digestive system surgical procedures[mesh] OR Urologic Surgical Procedures[mesh] OR Ureteral/surgery[mesh] OR Ureteral Obstruction/surgery OR Genitalia/surgery[mesh] OR Urogenital System/surgery[mesh] OR urogenital[tiab] OR genitourinary[tiab] OR urology[tiab] OR urological[tiab] OR urologic[tiab] OR ureteral obstruction[tiab] OR gastrointestinal[tiab] OR Fundoplication OR Nissen*[tiab] OR Pyeloplasty OR Pyeloplastic* OR Pyeloplasties	636098
#2	Search Robotics[mesh] OR robot* OR da vinci[tiab] OR zeus[tiab] OR telesurgical[tiab] OR tele-surgical[tiab] OR telesurgery[tiab] OR tele-surgery[tiab] OR Surgery, Computer-Assisted [Mesh] OR computer assist*[tiab] OR computer-assist*[tiab] OR computer aided[tiab] OR computer-aided*[tiab] OR telerobot*[tiab] OR tele-robot*[tiab]	53860
#1	Search child[tiab] OR children[tiab] OR pediatric[tiab] OR paediatric[tiab] OR pediatrics[tiab] OR paediatrics[tiab] OR Adolescent[tiab] OR Adolescents[tiab] OR teen[tiab] OR teens[tiab] OR teenager[tiab] OR teenagers[tiab] OR Youth[tiab] OR Youths[tiab] OR young people[tiab] OR Young person[tiab] OR Infant[tiab] OR Infants[tiab] OR Toddler[tiab] OR Toddlers[tiab] OR Newborn[tiab] OR Neonate[tiab] OR Neonates[tiab] OR Babies[tiab]	1316553

Database: EMBASE (OVID SP)
Date: 2013-05-20
No of results: 391

#	Searches	Results
1	(Child or children or pediatric or paediatric or pediatrics or paediatrics or Adolescent or Adolescents or teen or teens or teenager or teenagers or Youth or Youths or young people or Young person or Infant or Infants or Toddler or Toddlers or Newborn or Neonate or Neonates or Babies).ti,ab,tw.	1532062
2	exp robotics/	19049
3	exp telesurgery/	159
4	exp computer assisted surgery/	5803
5	(Robot or robots or robotic or robotics or da vinci or zeus or telesurgical or tele-surgical or telesurgery or tele-surgery or computer assisted or computer-assisted or telerobot or telerobots or telerobotic or tele-robot or tele-robotic or computer-aided or computed aided).ti,ab,tw.	54357
6	2 or 3 or 4 or 5	61960
7	1 and 6	2498
8	exp abdominal surgery/	483941
9	exp gastrointestinal surgery/	225514
10	exp stomach surgery/	65108
11	exp stomach fundoplication/	6535
12	(Gastrointestinal or Fundoplication or Nissen).ti,ab,tw.	194774
13	8 or 9 or 10 or 11 or 12	653683

14	exp urologic surgery/	383419
15	exp urinary tract surgery/	183919
16	exp ureter surgery/	10355
17	exp urethra surgery/	7906
18	exp pyeloplasty/	2320
19	urogenital system/su [Surgery]	273
20	exp genital system/su [Surgery]	12361
21	exp urogenital system/su [Surgery]	24059
22	exp ureter obstruction/su [Surgery]	2239
23	(Genitourinary or Urogenital or urology or urological or urologic or pyeloplastic or Plastics or Pyeloplasty or Pyeloplasties or ureteral obstruction).ti,ab,tw.	82400
24	14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23	461110
25	13 or 24	1060021
26	7 and 25	430
27	**limit 26 to ((danish or english or icelandic or norwegian or swedish) and yr="2000 -Current")**	**391**

Database: The Cochrane Library
Date: 2013-05-21
No of results: 29
Cochrane reviews 1
Other reviews 1
Trials 21
Technology assessments 1
Economic evaluations 5

Search		**Items found**
#1	Child or children or pediatric or paediatric or pediatrics or paediatrics or Adolescent or Adolescents or Infant or Infants or Toddler or Toddlers or Newborn or Neonate or Neonates or babies: ti,ab,kw(Word variations have been searched)	136749
#2	MeSH descriptor: [Robotics] this term only	360
#3	robotics or Robot or robotic or da vinci or Telesurg* or telerobot* or telerobotic*	603
#4	#2 or #3	603
#5	**#1 and #4**	**29**
	From 2000 to 2013	

Database: CRD
Date: 2013-05-21
No of results: 11

Line	Search	Hits
1	MeSH DESCRIPTOR Robotics EXPLODE ALL TREES	159
2	(robot) OR (robotic) OR (robotics)	198
3	(Da vinci) OR (Telesurg*) OR (telerobot*)	37
4	#1 OR #2 OR #3	206
5	(child) OR (children) OR (newborn)	7591
6	(pediatric) OR (pediatrics) OR (paediatric)	2152
7	(Infant) OR (Infants) OR (Neonate)	3238
8	(toddler) OR (toddlers) OR (babies)	650
9	(neonates)	370
10	(paediatrics) OR (adolescent) OR (adolescents)	4151
11	#5 OR #6 OR #7 OR #8 OR #9 OR #10	10428
12	**#4 AND #11**	**11**

The web-sites of **SBU, Kunnskapssenteret** and **Sundhedsstyrelsen** were visited 2011-01-24
Nothing relevant to the question at issue was found.

Reference lists
A comprehensive review of reference lists brought 24 new records

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Appendix 2:1 – Included studies – design and patient characteristics – listed according to study design, alphabetically.
Robot-assisted laparoscopic pyeloplasty compared to laparoscopic pyeloplasty without robot-assistance, or open surgery.

Case-series were only used to record complications for robot-assisted surgery.

Author, Year, Country	**Study Design**	**Study Groups; Intervention (I) vs. control (C)**	**Follow-up period**	**Patients (n)**	**Age (years)***	**Male/female**	**Outcome variables**
Barbosa, 2013 USA	Cohort	I: Robot assisted pyeloplasty C: Open pyeloplasty	I=33 months C=31 months	212 (in total)	I=7.2 C=1.2	I=41/17 C=84/70	Resolution hydronephrosis Complications
Behan, 2011 USA	Cohort	I: Robot assisted pyeloplasty C: Open pyeloplasty	Not stated	44	I=10.3 C=7.3	Not stated	Hospital length of stay Operative time
Casella, 2013 USA	Cohort	: Robot assisted pyeloplasty C: Laparoscopic pyeloplasty	Not stated	46	I=8.5 C=6.9	Not stated	Hospital length of stay Operative time Complications
Franco, 2007 USA	Cohort	I: Robot assisted pyeloplasty C: Laparoscopic pyeloplasty	I=46 weeks C=36 weeks	29	I=11.6 C=11.8	Not stated	Conversion to open surgery Operative time Post-operative pain Resolution hydronephrosis Complications
Freilich, 2010 USA	Cohort	I: Robot assisted pyeloplasty C: Open pyeloplasty	I=11 months C=13 months	78	I=10.7 C=6.5	Not stated	Hospital length of stay Parental satisfaction Post-operative pain Surgery incision scar
Lee, 2006 USA	Cohort	I: Robot assisted pyeloplasty C: Open pyeloplasty	I=10 months C=20 months	66	I=7.9 C=7.6	I=23/10 C=17/16	Conversion to open surgery Hospital length of stay Operative time Post-operative pain Resolution hydronephrosis Complications

Appendix 2:1 – Included studies – design and patient characteristics – listed according to study design, alphabetically.
Robot-assisted laparoscopic pyeloplasty compared to laparoscopic pyeloplasty without robot-assistance, or open surgery.

Case-series were only used to record complications for robot-assisted surgery.

Riachy, 2013 USA	Cohort	I: Robot assisted pyeloplasty C: Laparoscopic pyeloplasty	I=22 months C=43 months	64	I=8.8 C=8.1	I=23/23 C=14/4	Conversion to open surgery Hospital length of stay Operative time Post-operative pain Resolution hydronephrosis Complications
Sorensen, 2011, USA	Cohort	I: Robot assisted pyeloplasty C: Open pyeloplasty	I=17 months C=19 months	66	I=9.2 C=8.2	I=10/23 C=10/23	Conversion to open surgery Hospital length of stay Operative time Post-operative pain Resolution hydronephrosis Complications
Subotic, 2012 Switzerland	Cohort	I: Robot assisted pyeloplasty C: Laparoscopic pyeloplasty	I=10 months C=21 months	39	I=9.6 C=0.9	I=13/6 C=14/6	Conversion to open surgery Hospital length of stay Operative time Resolution hydronephrosis Complications
Yee, 2006 USA	Cohort	I: Robot assisted pyeloplasty C: Open pyeloplasty	I=15 months C=53 months	16	I=9.8 C=11.5	I=7/1 C=4/4	Conversion to open surgery Hospital length of stay Operative time Post-operative pain Resolution hydronephrosis Complications
de Lambert, 2013 France	Case-series	Robot assisted pyeloplasty	18 months	17	5.8	Not stated	Complications
Herbst, 2013 USA	Case-series	Robot assisted pyeloplasty	Prospective (P)=16 months Retrospective (R)=42 months	39	P: 5.3 R: 3	P: 14/6 R: 15/4	Complications

Appendix 2:1 – Included studies – design and patient characteristics – listed according to study design, alphabetically.
Robot-assisted laparoscopic pyeloplasty compared to laparoscopic pyeloplasty without robot-assistance, or open surgery.

Case-series were only used to record complications for robot-assisted surgery.

Minnillo, 2011 USA	Case-series	Robot assisted pyeloplasty	32 months	155	10.5	112/43	Complications
Najmaldin, 2007 UK	Case-series	Robot assisted pyeloplasty	Not stated	13	10.2 (all cases)	Not stated	Complications
O`Brien, 2012 USA	Case-series	Robot assisted pyeloplasty	66 weeks	20	7.4	10/10	Complications
Olsen, 2007 Denmark	Case-series	Robot assisted pyeloplasty	12 months	65	7.9	49/18	Complications
Rodriguez, 2012 USA	Case-series	Robot assisted pyeloplasty	16 months	12	9.1	Not stated	Complications
Singh, 2012 India	Case-series	Robot assisted pyeloplasty	29 months	34	12	27/7	Complications
Volfson, 2007 USA	Case-series	Robot assisted pyeloplasty	Not stated	26	9.0	Not stated	Complications

* Mean or median age, as stated in the publication.

Appendix 2:2 – Included studies – design and patient characteristics – listed according to study design, alphabetically.
Robot-assisted laparoscopic fundoplication compared to laparoscopic fundoplication without robot-assistance, or open surgery.

Case-series were only used to record complications for robot-assisted surgery.

Author, Year, Country	Study Design	Study Groups; Intervention (I) vs. control (C)	Follow-up period	Patients (n)	Age (years)*	Male/ female	Outcome variables
Albassam, 2009 Saudi Arabia	Cohort	I: Robot assisted fundoplication C1: Laparoscopic fundoplication	14 months	50	I=5.2 C1=3.8	I=11/14 C1=9/16	Conversion to open surgery Length of hospital stay Need of reoperation Operative time Post-operative pain Symptom resolution Complications
Anderberg, 2007 Sweden	Cohort	I: Robot assisted fundoplication C1: Laparoscopic fundoplication C2: Open fundoplication	1 month (1 year for some data)	18	I=7 C1=11 C2=4	I=5/1 C1=3/3 C2=4/2	Conversion to open surgery Length of hospital stay Operative time Post-operative pain Symptom resolution Complications
Anderberg, 2009 Sweden	Cohort	I: Robot assisted fundoplication C1: Laparoscopic fundoplication C2: Open fundoplication	Not stated	34	I=14 C1=10 C2=10	I=11/3 C1=6/4 C2=5/5	Conversion to open surgery Length of hospital stay Operative time Post-operative pain
Copeland, 2008 USA	Cohort	I: Robot assisted fundoplication C1: Laparoscopic fundoplication C2: Open fundoplication	30 days	150	I=9.8 C1=8.9 C2=7.1	Not stated	Conversion to open surgery Length of hospital stay Need of reoperation Operative time Symptom resolution Complications
Lehnert, 2006 Germany	Cohort	I: Robot assisted fundoplication C1: Laparoscopic fundoplication	Up to 14 months	20	I=11.2 C1=7.7	Not stated	Conversion to open surgery Need of reoperation Operative time Symptom resolution Complications

Appendix 2:2 – Included studies – design and patient characteristics – listed according to study design, alphabetically.
Robot-assisted laparoscopic fundoplication compared to laparoscopic fundoplication without robot-assistance, or open surgery.

Case-series were only used to record complications for robot-assisted surgery.

Author, Year, Country	**Study Design**	**Study Groups; Intervention (I) vs. control (C)**	**Follow-up period**	**Patients (n)**	**Age (years)***	**Male/ female**	**Outcome variables**
Alqahtani 2010 Saudi Arabia	Case-series	Robot assisted fundoplication	Not stated	39	8.9 (all cases)	Not stated	Complications
de Lambert, 2013 France	Case-series	Robot assisted fundoplication	18 months	29	8.3	Not stated	Complications
Klein, 2007 USA	Case-series	Robot assisted fundoplication	Not stated	25	Not stated	Not stated	Complications
Knight 2004 USA	Case-series	Robot assisted fundoplication	Not stated	15	4.3	Not stated	Complications
Margaron, 2010 USA	Case-series	Robot assisted fundoplication	32 months	15	8	Not stated	Complications
Meehan, 2007 USA	Case-series	Robot assisted fundoplication	18 months	50	5.1	Not stated	Complications
Meehan, 2008 USA	Case-series	Robot assisted fundoplication	Not stated	34	8.4 (all cases)	Not stated	Complications
Najmaldin, 2007 UK	Case-series	Robot assisted fundoplication	Not stated	11	10.2 (all cases)	Not stated	Complications

* Mean or median age, as stated in the publication.

Project: Robotic surgery for fundoplication or pyeloplasty in children

Appendix 3 Excluded articles

Study (author, publication year)	Reason for exclusion
Barbosa, 2012	Wrong intervention (evaluates patient or parent preferences for different scars from pictures).
Camps, 2011	Mixed interventions.
Cundy, 2013	Data not presented separately for pyeloplasty and fundoplication.
Gutt, 2002	<10 fundoplication only patients.
Lindgren, 2012	Case series with <10 patients with robotic surgery
Luebbe, 2003	<10 fundoplication only patients.
Meehan, 2009	Mixed interventions (feasibility for small children).
Olsen, 2004	Duplicate publication (same patients reported in Olsen, 2007).
Rowe, 2012	Mixed interventions and patient groups.

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty

Appendix 4:1

Outcome variable: Resolution of hydronephrosis

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Barbosa, 2013	USA	Cohort	I=52 C2=53	0	40/52 (77%)	Not studied	36/53 (68%) ns.	Outcome: improvement on ultrasound. Median follow-up (for the matched groups): Robot assisted: 34 months (range 12.3-92 months); open surgery: 36 months (range 13.5-88 months).	?	?	-
Franco, 2007	USA	Cohort	I=15 C1=12	0	14/15 (93.3%)	12/12 (100%)	Not studied	Outcome: improvement on ultrasound. One patient in robot assisted group showed flank pain after hydration after 72 weeks. Subsequent ultrasounds revealed no hydronephrosis. Mean follow-up, robot assisted: 46 weeks (range 8-122 weeks); laparoscopic surgery: 36 weeks (range 10-120 weeks).	?	-	-
Lee, 2006	USA	Cohort	I=33 C2=33	0	26/33 (79%)	Not studied	32/33 (97%)	Outcome: improvement on ultrasound. Mean follow-up, robot assisted: 10 months (range 0.4-28 months); open surgery: 20 months (range 1-57 months).	?	?	-
Riachy, 2013	USA	Cohort	I=46 C1=18	0	39/46 (85%)	17/18 (95%) ns.	Not studied	Outcome: improvement on ultrasound. Median follow-up, robot assisted: 22 months (2-36 months); laparoscopic surgery: 43 months (range 13-53 months).	?	?	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty
Appendix 4:1
Outcome variable: Resolution of hydronephrosis

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery (I)	Result: Laparoscopic surgery (C1)	Result: Open surgery (C2)	Comments	Directness*	Study limitations *	Precision *
Sorensen, 2011	USA	Cohort	33+33	0	32/33 (97%)	Not studied	32/33 (97%)	Improved drainage on MAG3 renography,and or improved hydronephrosis combined with renal parenchymal growth on ultrasound or CT, and resolution of renal colic crisis in patients with pain. Mean±SD follow-up, robot assisted: 17±9 months; open surgery: 19±17 months.	-	?	-
Subotic, 2012	Switzerland	Cohort	I=19 C1=20	0	Mean pelvis diameter mm (range): Preop: 26 (7-60) Postop: 11(5-27) $p<0.05$ within group	Mean pelvis diameter mm (range): Preop:24 (8-45) Postop: 11(2-18) $p<0.05$ within group	Not studied	MAG3 renography and ultrasound pre- and post-operatively. All patients (100%) had resolution of symptoms One transient obstruction was observed in both groups. Mean follow-up, robot assisted: 10 months (range 6-24 months); laparoscopic surgery: 21 months (range 6-48 months).	-	-	-
Yee, 2006	USA	Cohort	8+8	0	8/8 (100%)	Not studied	7/8 (88%) 1 obstruction ns.	Renography and/or ultrasound Mean follow-up, robot assisted: 14.7 months (range 2-24 months); open surgery: 53.2 months (range not stated).	-	-	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty

Appendix 4:2

Outcome variable: Post-operative pain

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Franco, 2007	USA	Cohort	I=17 C1=12	I=2	All patients were pain free postoperatively	All patients were pain free postoperatively	Not studied		?	-	-
Freilich, 2010	USA	Cohort	I=31 C2=47	I=17 C2=32	Mean score: 4.1 Median score: 4	Not studied	Mean score: 3.6 Median score: 4 ns. between groups	Questionnaire survey Scores for parent satisfaction: 1 (very dissatisfied) to 5 (very satisfied)	?	?	-
Lee, 2006	USA	Cohort	I=33 C2=33	0	Morphine Mean: 0.8 mg/kg Range: 0.0-2.0 mg/kg	Not studied	Morphine Mean: 2.5 mg/kg Range: 0.1-13.4 mg/kg p<0.001 between groups	Narcotic requirements postoperatively per day.	?	?	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty
Appendix 4:2
Outcome variable: Post-operative pain

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Riachy, 2013	USA	Cohort	I=46 C1=18	0	Morphine Mean: 0.052 mg/kg Range: 0-0.24 mg/kg Ketorolac Mean: 0.25 mg/kg Range: 0-2.73 mg/kg Acetaminophen Mean: 14.9 mg/kg Range: 0-47.7 mg/kg	Morphine Mean: 0.067 mg/kg Range: 0-0.39 mg/kg p=0.417 between groups Ketorolac Mean: 0.001 mg/kg Range: 0-1.14 mg/kg p=0.04 between groups Acetaminophen Mean: 12.1 mg/kg Range: 0-45.2 mg/kg p=0.96 between groups	Not studied	Narcotic requirements postoperatively per day. Analgetics requirements postoperatively per day.	?	?	-
Sorensen, 2011	USA	Cohort	I=33 C2=33	0	No difference in post-operative pain scores. Data not shown.	Not studied	No difference in post-operative pain scores. Data not shown.	Pain score 0-10 Data not extractable	-	?	-
Yee, 2006	USA	Cohort	I=8 C2=8	0	Morphine Mean: 7,4 mg Range: 0-23 mg	Not studied	Morphine Mean: 22.0 mg Range: 0-100 mg p=0.31 between groups	Narcotic requirements (morphine equivalents) postoperatively per day.	-	-	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty
Appendix 4:3
Outcome variable: Length of hospital stay

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Behan, 2011	USA	Cohort	I=37 C2=7	0	Mean (sem): 1.6 (0.1) days	Not studied	Mean (sem): 2.8 (0.5)days ns.		-	-	-
Casella, 2013	USA	Cohort	I=23 C1=23	0	All patients discharged home on postoperative day 1	All patients discharged home on postoperative day 1	Not studied		?	-	-
Freilich, 2010	USA	Cohort	I=31 C2=47	I=17 C2=32	Mean: 2.4 days Range: 0.5-5.5	Not studied	Mean: 4.0 days Range: 1.7-11.4 p=0.001		?	?	-
Lee, 2006	USA	Cohort	I=33 C2=33	0	Mean: 2.3 days Range: 0.5-6.0	Not studied	Mean: 3.5 days Range: 2.7-5.0 p<0.001		?	?	-
Riachy, 2013	USA	Cohort	I=46 C1=18	0	Median: 2 days Range: 1-6	Median: 1 day Range: 1-4 ns.	Not studied		?	?	-
Sorensen, 2011	USA	Cohort	I=33 C2=33	0	Mean (sd): 2.2 (1.6) days	Not studied	Mean (sd): 2.6 (0.7) days ns.		-	?	-
Subotic, 2012	Switzerland	Cohort	I=19 C1=20	0	Mean: 6 days Range: 4-12	Mean: 7 days Range: 5-12 ns.	Not studied		-	-	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty

Appendix 4:3

Outcome variable: Length of hospital stay

*	+ No problem ? Some problems - Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Yee, 2006	USA	Cohort	I=8 C2=8	0	Mean: 2.4 days Range: 1-5	Not studied	Mean: 3.3 days Range: 1-8 ns.		-	-	-

Pediatric robotically assisted surgery vs. open surgery for pyeloplasty

Appendix 4:4

Outcome variable: Incision scar

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery (I)	Open surgery (C)				
Freilich, 2010	USA	Cohort	I=31 C=47	I=17 C=32	Mean score: 4.37 Median score: 5	Mean score: 3.83 Median score: 4 p=0.02	Questionnaire survey Scores for parent satisfaction: 1 (very dissatisfied) to 5 (very satisfied)	?	?	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty
Appendix 4:5
Outcome variable: Conversion

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery (I)	Result: Laparoscopic surgery (C1)	Result: Open surgery (C2)	Comments	Directness*	Study limitations*	Precision*
Franco, 2007	USA	Cohort	I=17 C1=12	I=2	2/17 (12%) conversion to open surgery	No conversions	Not studied	In the robot assisted group the conversions were due to: Patient with a stone (n=1) Robot malfunction (n=1)	?	-	-
Lee, 2006	USA	Cohort	I=33 C2=33	0	No conversions to open or standard laparoscopic surgery	Not studied	Not applicable		?	?	-
Riachy, 2013	USA	Cohort	I=46 C1=18	0	No conversions to open surgery	No conversions to open surgery	Not studied		?	?	-
Sorensen, 2011	USA	Cohort	I=33 C2=33	0	2 conversions completed with conventional laparoscopy. 1 conversion to conventional laparoscopy for 1.5h, and then completed robotically. No conversions to open surgery	Not studied	Not applicable	Three mechanical failures developed in patients with robotic pyeloplasty.	-	?	-
Subotic, 2012	Switzerland	Cohort	I=19 C1=20	0	No conversions to open surgery	No conversions to open surgery	Not studied		-	-	-
Yee, 2006	USA	Cohort	I=8 C2=8	0	No conversions to open surgery	Not studied	Not applicable		-	-	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty
Appendix 4:6
Outcome variable: Operative time

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery (I)	Result: Laparoscopic surgery (C1)	Result: Open surgery (C2)	Comments	Directness*	Study limitations*	Precision*
Behan, 2011	USA	Cohort	I=37 C2=7	0	Mean (sem): 203 (7.7) min	Not studied	Mean (sem): 164 (14.6) min p=0.02		-	-	-
Casella, 2013	USA	Cohort	I=23 C1=23	0	All operations: 200 min (n=23) Retrograde stent: 246 min (n=13) Antegrade stent: 140 min (n=10)	All operations: 265 min (n=23) p= 0.001 ns. p=0.00001	Not studied	Robot assisted surgery cases in total, and with different stent placements, were compared with all laparoscopic surgery cases.	?	-	-
Franco, 2007	USA	Cohort	I=17 C1=12	I=2	Mean (sd): 223 (46.5) min Range: 150-290	Mean(sd): 237 (24.1) min Range: 200-285 ns.	Not studied	Two aborted operations in the robot assisted group: patient with a stone (n=1), due to robot malfunction (n=1).	?	-	-
Lee, 2006	USA	Cohort	I=33 C2=33	0	Mean: 219 min Range: 133-401	Not studied	Mean: 181 min Range: 123-308 p=0.03	In the robot assisted group, more patients underwent cystoscopy, and more patients had ureteral stents.	?	?	-
Riachy, 2013	USA	Cohort	I=46 C1=18	0	Median: 209 min Range: 106-540	Median: 298 min Range: 145-387 p=0.008	Not studied		?	?	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for pyeloplasty
Appendix 4:6
Outcome variable: Operative time

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Sorensen, 2011	USA	Cohort	I=33 C2=33	0	Mean (sd): 326 (77) min	Not studied	Mean(sd): 236 (24) min p=0.004	More urethral stents in the robot assisted group: 32/33 (97%), compared to open surgery group: 12/33 (36%).	-	?	-
Subotic, 2012	Switzerland	Cohort	I=19 C1=20	0	165 minutes Range: 104-225	248 min Range: 165-334 p<0.05	Not studied	Patients in the robot assisted group had antegrade stents, whereas patients in the laparoscopic group had retrograde stents.	-	-	-
Yee, 2006	USA	Cohort	I=8 C2=8	0	363 min Range: 255-522	Not studied	248 min Range: 144-375 p=0.03		-	-	-

Pediatric robotically assisted surgery vs. open surgery for pyeloplasty

Appendix 4:7

Outcome variable: Parental satisfaction

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Open surgery (C2)				
Freilich, 2010	USA	Cohort	I=31 C2=47	I=17 C2=32	Mean score: 4.8 Median score: 5	Mean score: 4.6 Median score: 5 ns.	Questionnaire survey Scores for parent satisfaction: 1 (very dissatisfied) to 5 (very satisfied)	?	?	-

Project: Robotically assisted surgery for pyeloplasty in children

Appendix 4:8

Outcome variable: Complications

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery (I)	Result: Laparoscopic surgery (C1)	Result: Open surgery (C2)	Comments	Directness*	Study limitations*	Precision*
Barbosa, 2013	Brazil	Cohort	212 (58+154)	0	1/58 (1.7%)	Not studied	6/154 (3.9%) ns	Robot assisted surgery group: One redo pyeloplasty. Open surgery group: Two with postoperative urinoma, three requiring redo pyeloplasty, one perirenal collection (4.3% stated in the article?).	?	?	-
Casella, 2013	USA	Cohort	23+23	0	0/23 (0%)	0/23 (0%)	Not studied	No complications	?	-	-
Franco, 2007	USA	Cohort	15+12	0	Leakage: 1/15 (6.7%)	Leakage: 2/12 (16.7%) ns.	Not studied	One omental eviceration via drain site occurred, but not stated in which study group	?	-	-
Lee, 2006	USA	Cohort	33+33	0	1/33 (3.0%)	Not studied	0/33 (0%) ns.	Robot assisted surgery group (retroperitoneal approach): Anterior crossing vessels were not identified. Patient was re-operated robotically with transperitoneal approach.	?	?	-
Riachy, 2013	USA	Cohort	46+18	0	2/46 (4.3%)	2/18 (11%) ns.	Not studied	Robot assisted surgery group: Two temporary urine leaks Laparoscopic group: One iatrogenic liver puncture, and one migrated urethral stent.	?	?	-
Sorensen, 2011	USA	Cohort	33+33	0	5/33 (15%)	Not studied	3/33 (9%) ns.	Robot assisted surgery group: One gross hematuria obstructing the stent, four urine extravasations from anastomotic closure. Open surgery group: One pyelonephritis, one dehydration and pain, one stent migration.	-	?	-

Project: Robotically assisted surgery for pyeloplasty in children
Appendix 4:8
Outcome variable: Complications

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery (I)	Result: Laparoscopic surgery (C1)	Result: Open surgery (C2)	Comments	Directness*	Study limitations*	Precision*
Subotic, 2012	Switzerland	Cohort	19+20	0	Intraoperative: 1*/19 (5%) During hospitalization: 2/19 (11%) After discharge: 4/19 (21%)	Intraoperative: 0/20 (0%) ns. During hospitalization: 3/20 (15%) ns. After discharge: 2/20 (10%) ns.	Not studied	*Power failure in operating room (no consequences for the patient). Clavien grade 3b complications: Robot assisted surgery group; One omentum prolapse through port incision, one macrohematuria, one dislodgment of stent. Laparoscopic group; Two dislodgement of double-J stents, one severe dilatation of renal pelvis.	-	-	-
Yee, 2006	USA	Cohort	8+8	0	1/8 (12.5%)	Not studied	1/8 (12.5%)	Robot assisted surgery group: One postoperative ileus. Open surgery group: One uretropelvic junction stricture within 6 months after surgery.	-	-	-
de Lambert, 2013	France	Case-series	17	0	Intraoperative: 1/17 (5.8%) Postoperative: 5/17 (29%)	Not studied	Not studied	One robot assisted pyeloplasty was converted to open because of a too long operative time. Postoperative complications included three stent migrations.			
Herbst, 2013	USA	Case-series	39	0	1/39 (2.5%)	Not studied	Not studied	Robot assisted surgery failed in one patient. Needed repeat surgery.			

Project: Robotically assisted surgery for pyeloplasty in children
Appendix 4:8
Outcome variable: Complications

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Minnillo, 2011	USA	Case-series	155	0	Complication rate 17/155 (11%) Clavien grade 3: 12/155 (7.7%) Clavien grade 1-2: 5/155 (3.2%) Failed surgeries: 5/155 (3.2%)	Not studied	Not studied	No robotic malfunctions or system failures. The failed surgeries were recurrent obstructions requiring reoperation			
Najmaldin, 2007	UK	Case-series	13	0	1/13 (7.7%)	Not studied	Not studied	13 pyeloplasty cases included. One extravasation of urine due to stent dislodgement. Two conversions (fault with robotic arm, difficulty with stent insertion).			
O`Brien, 2011	USA	Case-series	20	0	0/20 (0%)	Not studied	Not studied				
Olsen, 2007	Denmark	Case-series	65	0	12/67 (18%) 67 procedures in 65 patients	Not studied	Not studied	Retroperitoneal approach. Two urinary tract infections, two hematuria, three stent displacements, four postoperative temporary nephrostomies, one conversion due to limits in the movement of the camera arm.			
Rodriguez, 2012	USA	Case-series	12	0	0/12 (0%)	Not studied	Not studied	Robot assisted surgery without stent.			

Project: Robotically assisted surgery for pyeloplasty in children

Appendix 4:8

Outcome variable: Complications

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Singh, 2012	India	Case-series	34	0	5/34 (15%)	Not studied	Not studied	One omentum herniation through the port site (Clavien grade 3a), one ileocaecal volvulus (Clavien grade 3b), one serosal tear of small bowel, one deterioration function of operated kidney (resulting in nephrectomy), one migrated stent.			
Volfson, 2007	USA	Case-series	26	0	2/26 (7.7%)	Not studied	Not studied	26 pyeloplasty cases included. One delayed return of bowel movements (no ileus). One robotic system malfunction (no 3D vision, but procedure completed without event).			

Pediatric robotically assisted surgery vs. laparoscopic surgery, or open surgery for fundoplication
Appendix 4:9
Outcome variable: Symptom resolution

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery	Laparoscopic surgery	Open surgery				
Albassam, 2009	Saudi Arabia	Cohort	I=25 C1=25	0	Completely resolved 16/25 (64%) Improved 9/25 (36%)	Completely resolved 15/25 (60%) Improved 10/25 (40%) ns.	Not studied	Relief of preoperative symptoms. Mean follow-up: 14 months (1-48 months)	?	?	-
Anderberg, 2007	Sweden	Cohort	I=6 C1=6 C2=6	0	6/6 (100%)	6/6 (100%)	6/6 (100%)	Resolution from gastroesophageal reflux symptoms.	-	-	-
Copeland, 2008	USA	Cohort	I=50 C2=50 C2=50	0	No transient symptoms 35/50 (70%)	No transient symptoms 36/50 (72%)	No transient symptoms 44/50 (88%) ns.	30-day follow-up: In article described as: 'Presence of transient symptoms' including dysphagia, abdominal pain, feeding aversion, and gas bloating.	?	-	-
Lehnert, 2006	Germany	Cohort	C1=10 C2=10	0	10/10 (100%)	10/10 (100%)	Not studied	During 14 months of follow-up, no recurrence of clinically relevant gastroesophageal reflux	?	-	-

Pediatric robotically assisted surgery vs. laparoscopic surgery, or open surgery for fundoplication

Appendix 4:10

Outcome variable: Postoperative pain

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery	Result: Laparoscopic surgery	Result: Open surgery	Comments	Directness*	Study limitations*	Precision*
Albassam, 2009	Saudi Arabia	Cohort	I=25 C=25	0	9/25 (36%)	7/25 (28%) ns.	Not studied	Post operative analgesic requirements: 1-2 doses meperidine, 1mg/kg/dose.	?	?	-
Anderberg, 2007*	Sweden	Cohort	I=6 C1=6 C2=6	0	Mean (sd): 1.3 (0) days Range: 1-3	Mean (sd): 1.5 (0.7) days Range: 1-2	Mean (sd): 3.8 (0.7) days Range: 5-8 p=0.002	Use of morphine (days) Gastrostomies were performed in robotic group (pre op: n=2, during op: n=1); laparoscopic group (pre op: n=1, during op: n=3), and open surgery group (pre op: n=2, during op: n=2).	-	-	-
Anderberg, 2009*	Sweden	Cohort	I=14 C1=10 C2=10	0	Mean (sd): 1.1 (0.9) days Range: 1-3	Mean (sd): 1.6 (0.7) days Range: 1-3	Mean (sd): 3.3 (0,9) days Range: 2-5 p<0.001	Use of morphine (days) Gastrostomies may have been performed (see Anderberg, 2007)	-	-	-

* Some patients may have been reported in both Anderberg 2007, and Anderberg 2009.

Pediatric robotically assisted surgery vs. laparoscopic surgery, or open surgery for fundoplication

Appendix 4:11

Outcome variable: Length of hospital stay

* + No problem
? Some problems
\- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery	Result: Laparoscopic surgery	Result: Open surgery	Comments	Directness*	Study limitations *	Precision *
Albassam, 2009	Saudi Arabia	Cohort	I=25 C=25	0	Mean (sd): 4.56 (1.08) days Range: 4-9	Mean (sd): 4.12 (1.16) days Range: 3-8 ns.	Not studied		?	?	-
Anderberg, 2007*	Sweden	Cohort	I=6 C1=6 C2=6	0	Mean (sd): 4±1.4 days Range: 1-7	Mean (sd): 3.5±0.7 days Range: 3-4	Mean (sd): 6.2 (0.7) days Range: 5-8 p=0.01	Gastrostomies were performed in robotic group (pre op: n=2, during op: n=1); laparoscopic group (pre op: n=1, during op: n=3), and open surgery group (pre op: n=2, during op: n=2).	-	-	-
Anderberg, 2009*	Sweden	Cohort	I=14 C1=10 C2=10	0	Mean (sd): 3.8 (1.9) days Range: 1-8	Mean (sd): 5.2 (3.0) days Range: 3-12	Mean (sd): 7.9 (2.8) days Range: 5-13 p=0.002	Gastrostomies may have been performed (see Anderberg, 2007)	-	-	-
Copeland, 2008	USA	Cohort	I=50 C1=50 C2=50	0	Mean (sd): 2.9 (4.5) days	Mean (sd): 3.54 (7.8) days	Mean (sd): 3.5 (2.8) days p<0.001 between robotically assisted and open surgery		?	-	-

* Some patients may have been reported in both Anderberg 2007, and Anderberg 2009.

Pediatric robotically assisted surgery vs. laparoscopic surgery, or open surgery for fundoplication

Appendix 4:12

Outcome variable: Need of reoperation

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations*	Precision*
					Robot assisted surgery	Laparoscopic surgery	Open surgery				
Albassam, 2009	Saudi Arabia	Cohort	I=25 C1=25	0	0/25 (0%)	0/25 (0%)	Not studied	Mean follow-up: 14 months (1-48 months)	?	?	-
Copeland, 2008	USA	Cohort	I=50 C1=50 C2=50	0	4/50 (8%)	3/50 (6%)	Not stated	Not reported as 'need of reoperation', but as most 'common complications' requiring esophagus dilatation. Other indications for reoperation, or reoperations for open surgery were not reported.	?	-	-
Lehnert, 2006	Germany	Cohort	I=10 C1=10	0	0/10	0/10	Not studied	Follow-up14 months.	?	-	-

Pediatric robotically assisted surgery vs. laparoscopic surgery for fundoplication
Appendix 4:13
Outcome variable: Conversion to open surgery

* + No problem
? Some problems
\- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery	Laparoscopic surgery				
Albassam, 2009	Saudi Arabia	Cohort	I=25 C=25	0	1/25 (4%)	2/25 (8%) ns.		?	?	-
Anderberg, 2007*	Sweden	Cohort	I=6 C=6	0	0/6 (0%)	0/6 (0%)		-	-	-
Anderberg, 2009*	Sweden	Cohort	I=14 C=10	0	0/14 (0%)	2/10 (20%) ns.		-	-	-
Copeland, 2008	USA	Cohort	I=50 C=50	0	2/50 (4%)	1/50 (2%) ns.		?	-	-
Lehnert, 2006	Germany	Cohort	I=10 C=10	0	0/10 (0%)	0/10 (0%)		?	-	-

* Some patients may have been reported in both Anderberg 2007, and Anderberg 2009.

Pediatric robotically assisted surgery vs. laparoscopic surgery, or open surgery for fundoplication
Appendix 4:14
Outcome variable: Operative time

* + No problem
? Some problems
\- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result: Robot assisted surgery	Result: Laparoscopic surgery	Result: Open surgery	Comments	Directness*	Study limitations*	Precision*
Albassam, 2009	Saudi Arabia	Cohort	I=25 C1=25	0	Mean (sd): 186.0 (21.1) min Range: 145-259	Mean (sd): 193.1 (26.6) min Range: 155-228 ns.	Not studied		?	?	-
Anderberg, 2007*	Sweden	Cohort	I=6 C1=6 C2=6	0	Mean (sd): 213 (81) min Range: 150-285	Mean (sd): 189 (13) min Range 140-257	Mean (sd): 121 (85) min Range: 73-215 p=0.03	Gastrostomies were performed in robotic group (pre op: n=2, during op: n=1); laparoscopic group (pre op: n=1, during op: n=3), and open surgery group (pre op: n=2, during op: n=2).	-	-	-
Anderberg, 2009*	Sweden	Cohort	I=14 C1=10 C2=10	0	Mean (sd): 207 (47) min Range: 145-285	Mean (sd): 207 (52) min Range: 140-285	Mean (sd): 129±43 min Range: 73-215 p=0.03	Gastrostomies may have been performed (see Anderberg, 2007)	-	-	-
Copeland, 2008	USA	Cohort	I=50 C2=50 C2=50	0	Mean (sd): 160 (61) min	Mean (sd): 107 (31) min	Mean (sd): 73 (27) min p<0.001 robotically assisted vs. open surgery		?	-	-
Lehnert, 2006	Germany	Cohort	I=10 C1=10	0	Mean (sd): 127.2 (24.9) min	Mean (sd): 128.9 (17.4) min ns.	Not studied		?	-	-

* Some patients may have been reported in both Anderberg 2007, and Anderberg 2009.

Project: Robotically assisted surgery for fundoplication in children

Appendix 4:15

Outcome variable: Complications

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Albassam, 2009	Saudi Arabia	Cohort	50	0	Intraoperative: 0/25 (0%) Postoperative: 2/25 (8%)	Intraoperative: 0/25 (0%) Postoperative: 2/25 (8%) ns.	Not studied	Robot assisted surgery group: Two delayed gastric emptying. Laparoscopic group: one delayed gastric emptying, one dysphagia.	?	?	-
Anderberg, 2007	Sweden	Cohort	18	0	0/6 (0%)	0/6 (0%)	0/6 (0%)		-	-	-
Copeland, 2008	USA	Cohort	150	0	7/50 (14%)	8/50 (16%)	5/50 (10%) ns.	The complications included: Hiatal hernia; tight wrap requiring dilatation (most common in robot and laparoscopic surgery); wound infection (most common in open surgery).	?	-	-
Lehnert, 2006	Germany	Cohort	20	0	0/10 (0%)	0/10 (0%)	Not studied	No intraoperative-, or postoperative complications	?	-	-
Alqahtani, 2010	Saudi Arabia	Case-series	39	0	2/39 (5.1%)	Not studied	Not studied	One esophageal perforation, two with transient dysphagia. No system failures			
de Lambert, 2013	France	Case-series	29	0	Intraoperative: 0/29 (0%) Postoperative: 2/29 (6.9%)	Not studied	Not studied	Only fundoplication included. Postoperatively: One reflux recurrence with breakdown of sutures, and one tight gastric wrap.			

Project: Robotically assisted surgery for fundoplication in children
Appendix 4:15
Outcome variable: Complications

* + No problem
? Some problems
\- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result			Comments	Directness*	Study limitations *	Precision *
					Robot assisted surgery (I)	Laparoscopic surgery (C1)	Open surgery (C2)				
Klein, 2007	USA	Case-series	25	0	1/25 (4.0%)	Not studied	Not studied	One system failure of the Zeus robot caused conversion to laparoscopic surgery.			
Knight, 2004	USA	Case-series	15	0	0/15 (0%)	Not studied	Not studied	Zeus robot system.			
Margaron, 2010	USA	Case-series	15	0	Intraoperative: 0/15 (0%) Postoperative: 7/15 (47%)	Not studied	Not studied	Postoperative: Four ileus, one pneumothorax, one postoperative bleeding, one with uncontrolled seizure disorder.			
Meehan, 2007	USA	Case-series	50	0	Intraoperative: 0/50 (0%) Postoperative: 7/50 (14%)	Not studied	Not studied	Postoperatively: Two ileus, two dysphagia, one wound infection, one gas bloat syndrome, one wrap breakdown.			
Meehan, 2008	USA	Case-series	34	0	2/34 (5.8%)	Not studied	Not studied	Only fundoplications included. One dysphagia, one wrap breakdown.			
Najmaldin, 2007	UK	Case-series	11	0	0/11 (0%)	Not studied	Not studied				

Appendix 5 - Summary of Findings

Outcome variable **Number of studies**	**Design**	**Study limitations**	**Consistency**	**Directness**	**Precision**	**Publication bias**	**Magnitude of effect**	**Absolute effect**	**Quality of evidence GRADE**
PICO 1: Pyeloplasty – Robotically assisted (I) vs laparoscopic surgery (C1)									
Resolution of hydronephrosis 3	3 Cohort	Some limitations (?)	Some inconsistency (?)	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	I= 85-94% C1=95-100%	⊕○○○
Postoperative pain 2	2 Cohort	Some limitations (?)	No inconsistency	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	Not applicable	⊕○○○
Length of hospital stay 3	3 Cohort	Some limitations (?)	No inconsistency	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	I=1-6 days C1=1-7 days	⊕○○○
Operative time 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	I=165-223 min C1=237-298 min	⊕○○○
Complications 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=0-11% C1=0-15%	⊕○○○

Appendix 5 - Summary of Findings

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Absolute effect	Quality of evidence GRADE
PICO 1: Fundoplication – Robotically assisted (I) vs laparoscopic surgery (C1)									
Symptom resolution 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=70-100% C1=60-100%	⊕◯◯◯
Postoperative pain 3	3 Cohort	Some limitations (?)	No inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	Not applicable	⊕◯◯◯
Length of hospital stay 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=2.9-4.6 days C1=3.5-5.2 days	⊕◯◯◯
Need of reoperation 3	3 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=0-8% C1=0-6%	⊕◯◯◯
Operative time 5	5 Cohort	Some limitations (?)	No inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=127-213 min C1=107-207 min	⊕◯◯◯
Complications 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=0-14% C1=0-16%	⊕◯◯◯

Appendix 5 - Summary of Findings

Outcome variable **Number of studies**	**Design**	**Study limitations**	**Consistency**	**Directness**	**Precision**	**Publication bias**	**Magnitude of effect**	**Absolute effect**	**Quality of evidence GRADE**
PICO 2: Pyeloplasty – Robotically assisted (I) vs open surgery (C2)									
Resolution of hydronephrosis 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	I=77-100% C2=68-97%	⊕◯◯◯
Postoperative pain 4	4 Cohort	Some limitations (?)	No inconsistency	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	Not applicable	⊕◯◯◯
Length of hospital stay 5	5 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=1.6-2.4 days C2=2.6-4.0 days	⊕◯◯◯
Incision scar 1	1 Cohort	Serious limitations (-1)	No inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	Unlikely	Not relevant	Median Score I = 5 C2=4	⊕◯◯◯
Conversion 6	6 Cohort	Some limitations (?)	No inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	Unlikely	Not relevant	I=0-12%	⊕◯◯◯

Appendix 5 - Summary of Findings

Outcome variable **Number of studies**	**Design**	**Study limitations**	**Consistency**	**Directness**	**Precision**	**Publication bias**	**Magnitude of effect**	**Absolute effect**	**Quality of evidence GRADE**
Operative time 4	4 Cohort	Some limitations (?)	No inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=203-363 min C2=164-248 min	⊕○○○
Overall parental satisfaction 1	1 Cohort	Serious limitations (-1)	No inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	Unlikely	Not relevant	Median Score I=5 C2=5	⊕○○○
Complications 4	4 Cohort	Some limitations (?)	Some inconsistency (?)	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	I=1.7-15% C2=0-12.5%	

Appendix 5 - Summary of Findings

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Absolute effect	Quality of evidence GRADE
PICO 2: Fundoplication – Robotically assisted (I) vs open surgery (C2)									
Symptom resolution 2	2 Cohort	Some limitations (?)	No inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=70-100% C2=88-100%	⊕○○○
Postoperative pain 2	2 Cohort	Some limitations (?)	No inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	Not applicable	⊕○○○
Length of hospital stay 3	3 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=2.9-4 days C2=3.5-7.9 days	⊕○○○
Conversion 5	5 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=0-4%	⊕○○○
Operative time 3	3 Cohort	Some limitations (?)	Some inconsistency (?)	Serious indirectness (-1)	Uncertain precision (?)	Unlikely	Not relevant	I=145-160 min C2=73-215 min	⊕○○○
Complications 3	3 Cohort	Some limitations (?)	Some inconsistency (?)	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	I=0-14% C1=0-10%	⊕○○○

HTA

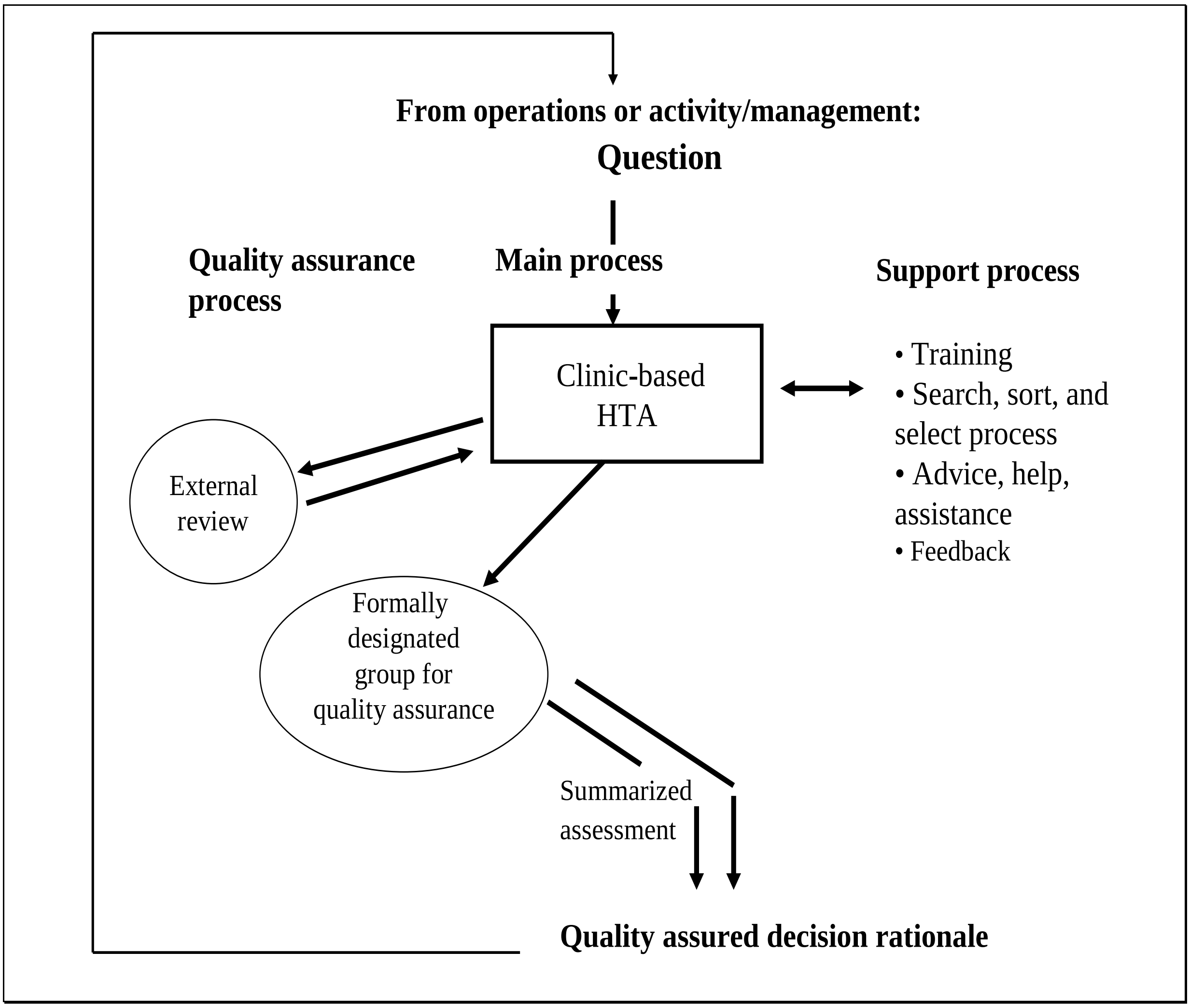
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE⊕⊕⊕⊕)
Moderate quality of evidence	= (GRADE ⊕⊕⊕O)
Low quality of evidence	= (GRADE ⊕⊕OO)
Very low quality of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either "strong" or "weak". This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh, Professor, MD.
Head of HTA-centrum


From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

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