BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-087519
Article Type:	Protocol
Date Submitted by the Author:	11-Apr-2024
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Keywords:	UROLOGY, Paediatric urology < PAEDIATRIC SURGERY, Systematic Review

Comparison of Outcomes of Open, Laparoscopic and Robot-assisted Laparoscopic Pyeloplasty in Children with Ureteropelvic Junction Obstruction: Protocol for a Systematic Review and Meta-Analysis

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Key Words: paediatric pyeloplasty, robotic surgery, minimally invasive, urology

Word Count: 1679

Competing Interests: J M Norris has received funding from the MRC (UK) and RCSEng. Abhisekh Chatterjee is institutionally affiliated with Imperial College London, which has a discounted Article Processing Charge (APC) agreement in place with BMJ Open.

Ethical approval: Not required

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Article type: Protocol for Systematic Review and Meta-Analysis

Short title: Comparison of Open, Laparoscopic, and Robotic Pyeloplasty in Children with PUJO: Protocol for a Systematic Review

Acknowledgements: None

Abstract

Introduction The treatment of children with pelviureteric junction obstruction (PUJO) has naturally progressed from open, to minimally invasive approaches, including laparoscopic pyeloplasty and robot-assisted laparoscopic pyeloplasty. The robot-assisted laparoscopic pyeloplasty (RALP) is now considered to be the gold standard in paediatric patients with PUJO, except in smaller infants due to size limitations.

Methods and analysis A systematic search of MEDLINE, PubMed, EMBASE and Cochrane databases will be conducted. Screening, data extraction, statistical analysis and reporting will be performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Included papers will be full text manuscripts written between 1947 and March 2024, comparing the outcomes and complications of open, laparoscopic, and robot-assisted laparoscopic pyeloplasties. Quality and study bias will be assessed using the Newcastle-Ottawa score. This present protocol is written in accordance with the PRISMA Protocol 2015 checklist, ensuring that the highest methodological standards are adhered to.

Ethics and dissemination No ethical approval shall be required as this is a review of the already published literature. Findings will be disseminated through publications in peer-reviewed journals and presentations at international and national conferences.

PROSPERO registration number CRD42023456779

Strengths and Limitations

1. Strength: Study selection, data extraction and quality assessment will be performed by two to three reviewers which will minimize the chances of bias influencing the results.
2. Limitation: Medical databases in other languages will not be searched because of language barriers, so language bias may exist.
3. Strength: Comparison of the three major pyeloplasty approaches ensures thorough representation of extant literature.

Background

Renal reconstruction surgery in the form of a dismembered pyeloplasty has been the gold standard of care for patients with ureteropelvic junction obstruction (PUJO) since Anderson and Hynes pioneered it in 1949 [1].

The introduction of minimally invasive procedures such as laparoscopic and robot-assisted laparoscopic pyeloplasty (RALP) for ureteropelvic junction obstruction (PUJO) represents a natural progression from Anderson's and Hynes's open dismembered pyeloplasty due to a reduction in operative and post-operative complications, and inpatient stay duration [2]. As such, RALP is now considered a new gold standard in paediatric minimally invasive surgery [3,4] and in all children, with the exception of small infants, the robotic approach appears to be very promising [5].

However, in some regions (including the developing world), the financial implications of robotic pyeloplasty are prohibitive, and as such, prior established approaches (i.e. open, laparoscopic) remain the surgical approaches of choice [3]. It is important to appreciate the degree of disparity in clinical outcome between different approaches to pyeloplasty, in order to drive changes in provision of paediatric surgical care.

The aim of this systematic review and meta-analysis is to provide a contemporary synthesis of the evidence surrounding paediatric PUJO surgery, comparing the key clinical outcomes between the dominant surgical approaches.

Methodology

This systematic review protocol has been written in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) 2015 checklist (Supplementary File 2) [6]. The study has been prospectively registered with PROSPERO review databases (CRD42023456779), and all methods described were established before implementation. Once identified the included studies will undergo analysis and thematic

synthesis to derive and compare the key outcomes of open, laparoscopic, and robot-assisted laparoscopic pyeloplasty in children with ureteropelvic junction obstruction.

Database Searches

A systematic search was conducted using PubMed, Ovid MEDLINE, Embase and Cochrane databases using the following search strategy using the following Medical Subject Headings (MeSH): (pyeloplasty) AND ((laparoscopic) OR (robotic) OR (open)) AND ((Ureteropelvic junction obstruction) OR (pelviureteric junction obstruction)) AND ((child) OR (p?ediatric)) AND (outcome). The search was conducted from inception to March 2024. No language filters were applied. To facilitate the initial screening process, Rayyan will be employed, an AI powered application designed to improve the reporting accuracy and speed of systematic reviews. Identified articles will be uploaded to Rayyan to expedite the initial screening process and allow two reviewers to filter duplicate studies and then subsequently screen the articles for relevance [7]. In addition, studies identified manually by the authors (PN, NC, JMN) will be retrieved and uploaded to Rayyan to be included in the screening process.

Study selection and data extraction

The title and abstract screening process will be completed independently by two researchers (PN and NC). Titles and abstracts of eligible studies will be assessed, and irrelevant articles will be removed. A full-text version of relevant articles will be downloaded for further eligibility review. Full-text review will be undertaken by two researchers (PN and NC), with disputes amongst researchers being discussed in a meeting and resolved by consensus, or arbitrated by a third author (NZ). The reasoning for excluding articles at the full-text review stage will be documented within Preferred Reporting Items for Systematic Reviews and

Meta-Analyses (PRISMA) flow diagram, an exemplar for which is below. Data extraction will be undertaken by three authors (PN, NC, AC).

Inclusion and exclusion criteria

To be included in the analysis, studies must investigate children under the age of 16 with PUJO undergoing a pyeloplasty. Studies or case series with a sample size of less than 10 total patients will be excluded in order to minimise heterogeneity and increase the statistical power of the meta-analysis. Conference abstracts, letters to the editor, case reports, reviews and expert opinions will be excluded. Studies that include patients older than 16 years of age will be excluded. Unpublished studies will not be sought. In addition, studies identified manually by the authors (PN, NC, JMN) will be retrieved and uploaded to Rayyan to be included in the screening process. Complete details of the eligibility criteria can be found in Table 1.

Table 1: Eligibility Criteria as outlined by the PICOS framework

	Eligibility Criteria
P – Population	Patients under the age of 16 years with PUJO undergoing a pyeloplasty (singular pathology or procedure)
I – Intervention	• Open Pyeloplasty • Laparoscopic Pyeloplasty • RALP
C – Comparator	No controls - comparisons will be between surgical approaches
O – Outcome	Operative success, Re-operation, Conversion, Postoperative complications, Estimated Blood Loss, Length of Stay, Operating Time, Analgesia requirement, Cost
S – Study Design	• RCTs

	• Cohort Studies • Case Series reporting 10 or more patients

Data extraction

The extracted data will be collated in a data sheet (Supplementary File 1). Data will be extracted by a minimum of one reviewer (PN, NC, AC) with any disagreements resolved by discussion. Relevant figures will be extracted from the data. If these are not provided, attempts will be made to calculate them from provided data. If this is not possible, the corresponding authors of each paper will be contacted to provide the relevant data. For studies not provided in English, an English language copy will be sought. If this is not successful, the authors will be contacted directly to obtain a translated version.

Risk of bias in individual studies

To assess bias and quality of the included studies a Newcastle-Ottawa score will be used, designed to assess cohort studies [8]. This scoring system is split into three main sections: selection, comparability, and outcome. Each of the sections contains sub-questions that assess the quality of the research methodology, at the study level. Three of the reviewers (PN, AC and NC) will be involved with this process, and any disagreement will be solved by consensus. These results of the risk of bias assessment will be utilised to carry out a sensitivity analysis, excluding studies deemed to be at a high risk of bias.

Meta-analysis

The nature of our research question means that there are three distinct comparisons to be made: open vs laparoscopic pyeloplasty, laparoscopic vs robotic pyeloplasty and open vs robotic pyeloplasty. As such, three meta-analyses will be conducted for each outcome of

interest, given sufficient homogeneity in identified studies' reported outcomes. We will extract the raw numbers of each relevant outcome in both groups. Odds Ratios (for binary outcomes) or standardised mean differences (SMDs; for continuous outcomes) will be calculated and pooled. Between study heterogeneity will be assessed using τ^2, Higgins and Thompsons I^2 statistic and Cochran's Q. Given significant between-study heterogeneity, a random-effects model with the Knapp-Hartung (KH) adjustment will be used to calculate a pooled effect measure using the generic inverse-variance method. Otherwise, a fixed-effects model using the exact Mantel-Haenszel method will be utilised. τ^2 will be calculated using the Paule-Mandel or restricted maximum likelihood estimator (REML) methods for binary or continuous outcome data respectively.

For studies with only one experimental group, proportions of each outcome of interest will be extracted and a meta-analysis of proportions carried out as per Wang et al. if more than three studies report sufficiently homogenous outcomes in this manner [9]. Proportions will first undergo logit transformation before being pooled using the generalised linear mixed-effects model (GLMM), with the KH adjustment applied. τ^2 will be obtained using the maximum-likelihood estimator. Studies with three experimental groups will be split into two separate 'arms' and their respective proportions of each outcome extracted, with the sample size of the control group halved in order to attribute half the weighting to each study. The validity of this assumption and impact on pooled proportions will be tested in a sensitivity analysis.

For each meta-analysis, identification of outliers and influencer analysis will be undertaken if there is deemed to be significant between-study heterogeneity. Influencer analysis will take place in according to the Leave-One-Out method. Influential studies will be identified using a random-effects model. Influencer analysis will be visualised using a Baujat plot and plots of Influence Diagnostics (including externally standardised residuals, DFFFITS value, Cook's

distance, Covariance ratio, Leave-One-Out τ^2 and Q values, hat values and study weights). Overall effect and I^2 will be visualised in forest plots. Outliers and influential studies will be excluded from the meta-analysis as part of a sensitivity analysis. Publication bias will be assessed using funnel plots. Given sufficient homogeneity of reported outcomes and enough studies reporting outcomes on infants (children <1 year of age), a subgroup analysis will be undertaken to identify any differences in outcomes between infants and children over 1 year of age.

Data cleaning and visualisation will be undertaken in R using the tidyverse, dplyr and ggplot packages. Meta analyses will be conducted in R using the meta package in accordance with Harrer et al [10]. If there is insufficient data to conduct a meta-analysis, only thematic synthesis will be performed.

Patient and public involvement

The public and patients were not involved in the development of this systematic review and meta-analysis protocol.

Discussion

Dismembered pyeloplasty remains the gold standard of treatment of patients with PUJO [11]. However, the optimal method of surgical access has not yet been determined based on key postoperative outcomes. Given the relatively recent development of RALP, This triplicate comparison has not been evaluated in the literature yet [2]. Our review seeks to provide a comprehensive overview of the literature surrounding the three approaches to an Anderson-Hynes dismembered pyeloplasty, and evaluate their efficacy both in isolation and when compared against each other on the basis of key postoperative outcomes.

The importance of this comparison cannot be understated. Determining the standard of care is a monumental undertaking, especially when the significant costs associated with robotic surgery (both in its undertaking and in the training of surgeons) are considered. For example, the standard of care for children with PUJO is a RALP in the UK; however, this is not yet the case in less affluent nations [3]. If children undergoing RALP for PUJO are demonstrated to experience definitively better outcomes than children undergoing laparoscopic or open pyeloplasty, then children from poorer nations face worse surgical outcomes on the basis of their socioeconomic status. If, however, RALP is demonstrated to have similar or identical outcomes to open and laparoscopic techniques, then the additional cost of the procedure is made negligible [13]. A decision to switch to a more expensive procedure cannot be made without careful comparisons between the three groups, which our paper aims to highlight.

In the coming years we are likely to see a rise in the number of RALPs performed in children around the world, and as such, we should aim to better understand the indications and outcomes of this procedure in children. Through systematic review and meta-analysis we aim to identify commonality between studies that have investigated the outcomes of RALP and compared it to open or laparoscopic pyeloplasty.

In summary, in our systematic review and meta-analysis we strive to derive the most prominent themes and collate extant evidence from studies that compare open, laparoscopic and robot-assisted laparoscopic pyeloplasty in paediatric patients. Synthesis of these studies will enhance our current understanding of the role of RALP in children with PUJO and will clarify the most pertinent areas for future research following the quick technological advancement in adult surgery and urology.

Trial status

Preliminary searches: started.

Piloting of the study selection process: started.

Formal screening: started.

Data extraction: not started.

Risk of bias assessment: not started.

Data analysis: not started.

Draft of search strategy for MEDLINE, EMBASE, PubMed and Cochrane databases

(pyeloplasty) AND ((laparoscopic) OR (robotic) OR (open)) AND ((Ureteropelvic junction obstruction) OR (pelviureteric junction obstruction)) AND ((child) OR (p?ediatric)) AND (outcome)

Ethics Statement

Due to the nature of the present study, no relevant ethical concerns or informed consent will be required. The protocol and systematic review and meta-analysis will be disseminated through publication in a peer reviewed journal.

Author statement

PN, ID, JMN, SB and NZ contributed to the conception of the study. The manuscript protocol was drafted by PN, and was revised by AC, NZ, JMN, NC, EK and IA. NZ will arbitrate the disagreements and ensure that no errors are introduced during the study. All authors approved the publication of the protocol. PN is the guarantor of the review.

Data availability statement

No public dataset was used in the creation of this manuscript. Upon publication of the final systematic review, statistical code for the meta-analysis will be made available.

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STUDY ID						
Record # ID	Title	Author	Year	Center	Country	Source of funding

STUDY				
Study period	Inclusion criteria (as in text)	Exclusion criteria (as in text)	Randomization method	Control group definition

Treatment group definition	Sample size (total)	Group size		age		
				mean		SI
		cotrol	treatment	control	treatment	control

PATIENTS						
	males (%)		Weight (kg)			
D			mean		SD	
treatment	control	treatment	control	treatment	control	treatment

BMI				Right side (n)		Left si
mean		SD				
control	treatment	control	treatment	control	treatment	control

PUJO						
de (n)	Aetiology				Haematuria	
	Intrinic		Extrinsic			
treatment	control	treatment	control	treatment	control	treatment

rUTIs		Pain		Failure to thrive (n)		Pre-op imagir used (t
control	treatment	control	treatment	control	treatment	control

erative ng test type of		Previous operation (% and type)		Renal anatomical anomalies (type		single kidney (%)	
	treatment	control	treatment	control	treatment	control	treatment

Malfunctioning kidney (n) <20% split function		Pre-pyeloplasty antibiotic prophylaxis (%		Post-pyeloplasty antibiotics (% and type given		intra-op antibio and typ
control	treatment	control	treatment	control	treatment	control

PRE PYELOPLASTY

ɔerative ɔtics (% e given		Pre-operative positive culture (% and microbe)		Moderate Hydronephrosis (n)		Severe Hydronephrosis (n)	
treatment	control	treatment	control	treatment	control	treatment	

Pre-natal US (grade of hydronephrosis)		AP Diameter (cm)				
		mean		median		SI
control	treatment	control	treatment	control	treatment	control

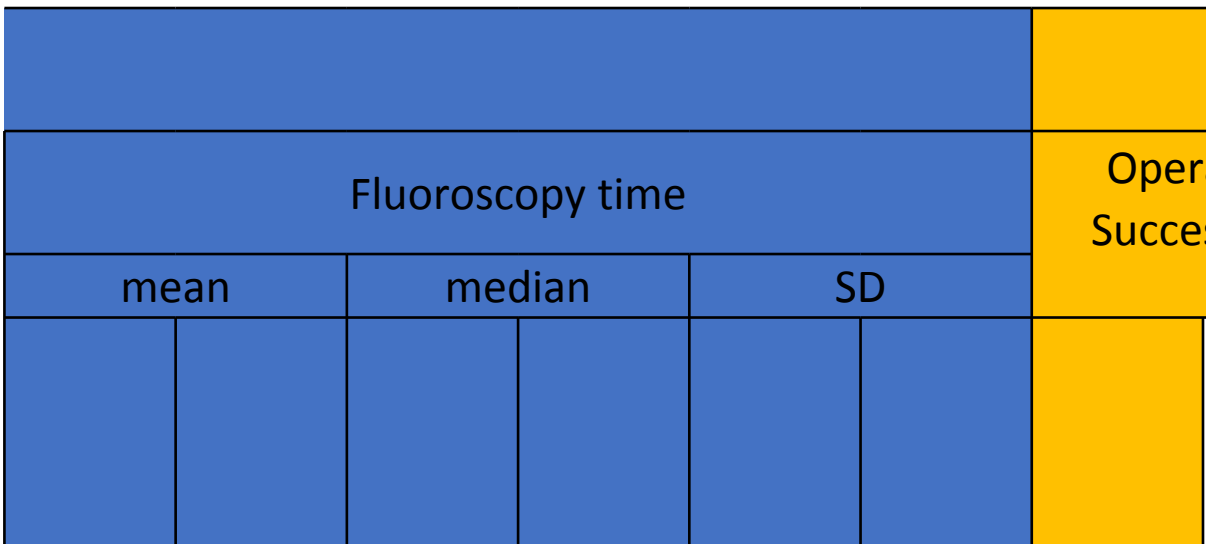
	MAG3 (t1/2 min)					
D	mean		median		SD	
treatment	control	treatment	control	treatment	control	treatment

Type of Robot		Number of ports		Daycase (n)		Anderso Pyelopl
control	treatment	control	treatment	control	treatment	control

n Hynes asty (n)		Retrograde Stent (n)		Antegrade Stent (n)		Nephrostomy (n)	
treatment	control	treatment	control	treatment	control	treatment	

PYELOPLASTY						
Intraoperative fluoroscopy (n)		Surgical Drain (n)		Retroperitoneal (n)		Intraop fluorosc
control	treatment	control	treatment	control	treatment	control

erative copy (n)		Operative Time (min)					
		mean		median		SD	
treatment	control	treatment	control	treatment	control	treatment	



ative ss (%)	Follow-up		AP Diameter (cm)			
			mean		median	
treatment	(timeline in months)	definition (imaging modality)	control	treatment	control	treatment

		MAG3 (t1/2 min)					
SD		mean		median		SI	
control	treatment	control	treatment	control	treatment	control	

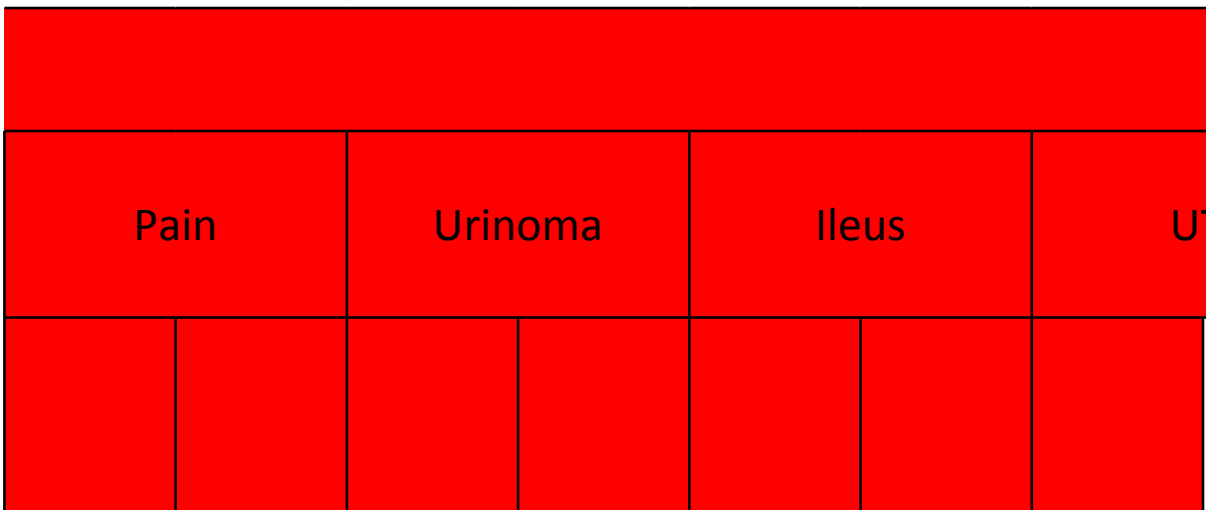
	O						
	Analgesia Requirement (mg/kg/hospital day)						
D	mean		median		SD		
	treatment	control	treatment	control	treatment	control	treatment

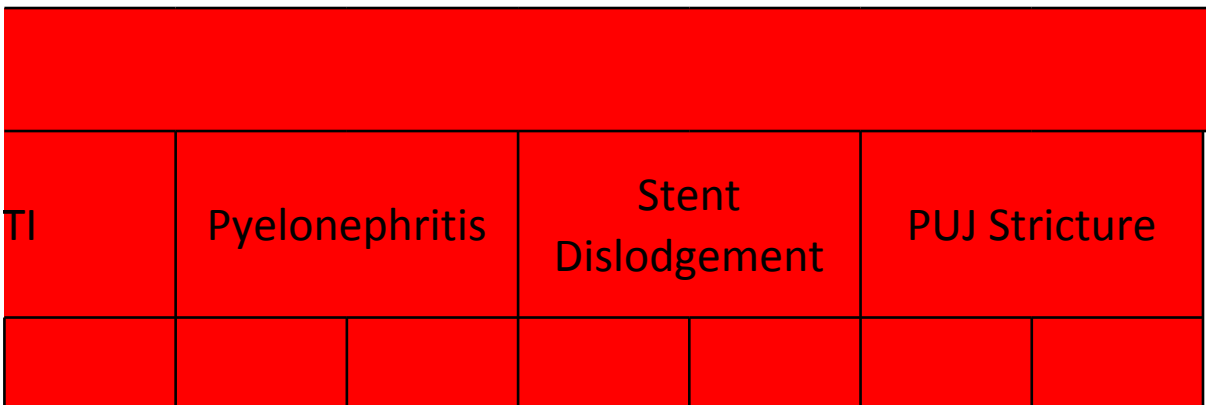
UTCOMES						
Length of stay (days)						
mean		median		SD		me
control	treatment	control	treatment	control	treatment	control

Stent dwell time (days)						
ean	median		SD		mean	
treatment	control	treatment	control	treatment	control	treatment

Cost (€)				EBL (		
median		SD		mean		mec
control	treatment	control	treatment	control	treatment	control

(mL)			A&E Attendance (n)		Readmission Rate (n)	
dian	SD					
treatment	control	treatment	control	treatment	control	treatment



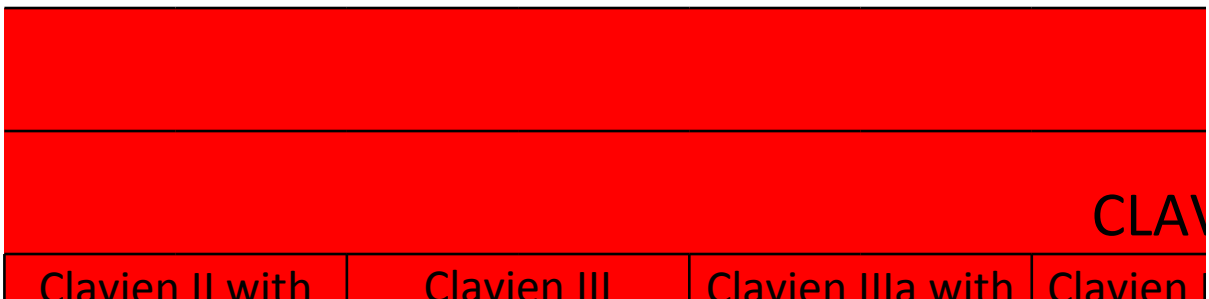


Transient flank pain		Conversion Rate (n)		Reoperation Rate (n)		Secor procedu (typ
control	treatment	control	treatment	control	treatment	control

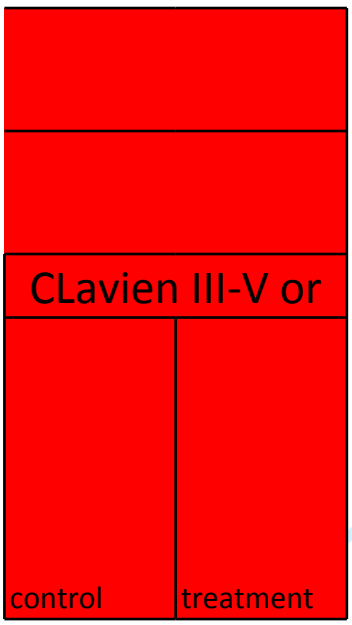
COMPLICATI						
ndary ure (n) , pe)	Fever (n)		Sepsis (n)		ITU admission (n)	
treatment	control	treatment	control	treatment	control	treatment

ONS						
Port Hernia (n)		Haematuria (n)		Microscopic Haematuria (n)		Urin Retent
control	treatment	control	treatment	control	treatment	control

nary ion (n)	HEMATOMA					
	(pain,		asymptomatic (pain		Clavien I with	
treatment	control	treatment	control	treatment	control	treatment



VIEN						
IIIb with	Clavien IV with		Clavien V (n)		Clavien I-II or	
treatment	control	treatment	control	treatment	control	treatment



STUDIES

	Representativeness of the exposed cohort		Selection of the non-
	Score	Text	Score

SELECTION

exposed cohort | Ascertainment of exposure

Text | Score | Text

Demonstration that outcome of interest was not present at the start of the study		Comparability of cohorts on the basis of the design or analysis	
Score	Text	Score	Text

OUTCOME

Assessment of outcome		Was follow-up long enough for outcomes to occur?		Adequacy of follow up of cohorts	
Score	Text	Score	Text	Score	Text

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	3
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	12

Amendments			
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support			
Sources	#5a	Indicate sources of financial or other support for the review	2
Sponsor	#5b	Provide name for the review funder and / or sponsor	N/A
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	5
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5, 7
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6, 7
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6, 7
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6

Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	S1
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	S1
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BMJ Open

Comparison of Outcomes of Open, Laparoscopic and Robot-assisted Laparoscopic Pyeloplasty in Children with Ureteropelvic Junction Obstruction: Protocol for a Systematic Review and Meta-Analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-087519.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Aug-2024
Complete List of Authors:	Nikolinakos, Panagiotis; Chelsea and Westminster Hospital NHS Foundation Trust, Department of Urology; School of Medicine, Attikon University Hospital, National and Kapodistrian University of Athens, 12462 Athens, Department of Pediatric Surgery Chatzikrachtis, Nikolaos; Chelsea and Westminster Hospital NHS Foundation Trust, Department of Urology Chatterjee, Abhisekh; Imperial College London Department of Medicine, School of Medicine Donkov, Ivo; Chelsea and Westminster Hospital NHS Foundation Trust, Department of Urology Bishara, Samuel; Chelsea and Westminster Hospital NHS Foundation Trust, Department of Urology Kotsi, Elisavet; Penteli Children's Hospital, 8 Ippokratous STR, 15236 Athens, , Department of Pediatrics Alexandrou, Ioannis; Penteli Children's Hospital, 8 Ippokratous STR, 15236 Athens, Department of Pediatric Surgery Zavras, Nikolaos; National and Kapodistrian University of Athens, Department of Pediatric Surgery Norris, Joseph M.; University College London
Primary Subject Heading:	Urology
Secondary Subject Heading:	Urology
Keywords:	UROLOGY, Systematic Review, Paediatric urology < PAEDIATRIC SURGERY

Comparison of Outcomes of Open, Laparoscopic and Robot-assisted Laparoscopic Pyeloplasty in Children with Ureteropelvic Junction Obstruction: Protocol for a Systematic Review and Meta-Analysis

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Key Words: paediatric pyeloplasty, robotic surgery, minimally invasive, urology

Word Count: 2220

Competing Interests: J M Norris has received funding from the MRC (UK) and RCSEng. Abhisekh Chatterjee is institutionally affiliated with Imperial College London, which has a discounted Article Processing Charge (APC) agreement in place with BMJ Open.

Ethical approval: Not required

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Article type: Protocol for Systematic Review and Meta-Analysis

Short title: Comparison of Open, Laparoscopic, and Robotic Pyeloplasty in Children with PUJO: Protocol for a Systematic Review

Acknowledgements: None

Abstract

Introduction The treatment of children with pelviureteric junction obstruction (PUJO) has naturally progressed from open, to minimally invasive approaches, including laparoscopic pyeloplasty and robot-assisted laparoscopic pyeloplasty. The robot-assisted laparoscopic pyeloplasty (RALP) is now considered to be the gold standard in paediatric patients with PUJO, except in smaller infants due to size limitations. Our systematic review aims to synthesise all the available evidence regarding key postoperative outcomes for the three surgical approaches to pyeloplasties in children. Our outcomes of interest include, but are not limited to, the reoperation rate, length of hospital stay, and postoperative complications as classified by the Clavien-Dindo grading system. A comprehensive assessment of all three methods in paediatric patients has yet to be conducted in the literature to date.

Methods and analysis A systematic search of MEDLINE, PubMed, EMBASE and Cochrane databases will be conducted. Screening, data extraction, statistical analysis and reporting will be performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Included papers will be full text manuscripts written between 1947 and March 2024, comparing the outcomes and complications of open, laparoscopic, and robot-assisted laparoscopic pyeloplasties. Quality and study bias will be assessed using the Newcastle-Ottawa score and, if relevant, the Cochrane Risk of Bias tool for Randomised Trials. This present protocol is written in accordance with the PRISMA Protocol 2015 checklist, ensuring that the highest methodological standards are adhered to.

Ethics and dissemination No ethical approval shall be required as this is a review of the already published literature. Findings will be disseminated through publications in peer-reviewed journals and presentations at international and national conferences.

PROSPERO registration number CRD42023456779

Strengths and Limitations

1. Strength: Study selection, data extraction and quality assessment will be performed by two to three reviewers which will minimize the chances of bias influencing the results.
2. Limitation: Medical databases in other languages will not be searched because of language barriers, so language bias may exist.
3. Strength: Comparison of the three major pyeloplasty approaches ensures thorough representation of extant literature.

Background

Renal reconstruction surgery in the form of a dismembered pyeloplasty has been the gold standard of care for patients with ureteropelvic junction obstruction (PUJO) since Anderson and Hynes pioneered it in 1949 [1].

The introduction of minimally invasive procedures such as laparoscopic and robot-assisted laparoscopic pyeloplasty (RALP) for ureteropelvic junction obstruction (PUJO) represents a natural progression from Anderson's and Hynes's open dismembered pyeloplasty due to a reduction in operative and post-operative complications, and inpatient stay duration [2]. As such, RALP is now considered a new gold standard in paediatric minimally invasive surgery [3,4] and in all children, with the exception of small infants, the robotic approach appears to be very promising [5].

However, in some regions (including the developing world), the financial implications of robotic pyeloplasty are prohibitive, and as such, prior established approaches (i.e. open, laparoscopic) remain the surgical approaches of choice [3]. It is important to appreciate the degree of disparity in clinical outcome between different approaches to pyeloplasty, in order to drive changes in provision of paediatric surgical care.

The aim of this systematic review and meta-analysis is to provide a contemporary synthesis of the evidence surrounding paediatric PUJO surgery, comparing the key clinical outcomes between the dominant surgical approaches.

Methodology

This systematic review protocol was written in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) 2015 checklist (Supplementary File 1) [6]. The study was prospectively registered with PROSPERO review databases (CRD42023456779), and all methods described were established before implementation. Once identified the included studies will undergo analysis and thematic

synthesis to derive and compare the key outcomes of open, laparoscopic, and robot-assisted laparoscopic pyeloplasty in children with ureteropelvic junction obstruction.

Database Searches

A systematic search was conducted using PubMed, Ovid MEDLINE, Embase and Cochrane databases using the following search strategy using the following Medical Subject Headings (MeSH): (pyeloplasty) AND ((laparoscopic) OR (robotic) OR (open)) AND ((Ureteropelvic junction obstruction) OR (pelviureteric junction obstruction)) AND ((child) OR (p?ediatric)) AND (outcome). The search was conducted from inception to March 2024. No language filters were applied. To facilitate the initial screening process, Rayyan will be employed, an AI powered application designed to improve the reporting accuracy and speed of systematic reviews. Identified articles will be uploaded to Rayyan to expedite the initial screening process and allow two reviewers to filter duplicate studies and then subsequently screen the articles for relevance [7]. In addition, studies identified manually by the authors (PN, NC, JMN) will be retrieved and uploaded to Rayyan to be included in the screening process.

Study selection and data extraction

The title and abstract screening process will be completed independently by two researchers (PN and NC). Titles and abstracts of eligible studies will be assessed, and irrelevant articles will be removed. A full-text version of relevant articles will be downloaded for further eligibility review. Full-text review will be undertaken by two researchers (PN and NC), with disputes amongst researchers being discussed in a meeting and resolved by consensus, or arbitrated by a third author (NZ). The reasoning for excluding articles at the full-text review stage will be documented within Preferred Reporting Items for Systematic Reviews and

Meta-Analyses (PRISMA) flow diagram, an exemplar for which is below. Data extraction will be undertaken by three authors (PN, NC, AC).

Inclusion and exclusion criteria

To be included in the analysis, studies must investigate children under the age of 16 with PUJO undergoing a pyeloplasty. Studies or case series with a sample size of less than 10 total patients will be excluded in order to minimise heterogeneity and increase the statistical power of the meta-analysis. Conference abstracts, letters to the editor, case reports, reviews and expert opinions will be excluded. Studies that include patients older than 16 years of age will be excluded. Unpublished studies will not be sought. In addition, studies identified manually by the authors (PN, NC, JMN) will be retrieved and uploaded to Rayyan to be included in the screening process. Complete details of the eligibility criteria can be found in Table 1.

Table 1: Eligibility Criteria as outlined by the PICOS framework

	Eligibility Criteria
P – Population	Patients under the age of 16 years with PUJO undergoing a pyeloplasty (singular pathology or procedure)
I – Intervention	• Open Pyeloplasty • Laparoscopic Pyeloplasty • RALP
C – Comparator	No controls - comparisons will be between surgical approaches
O – Outcome	Operative success, Re-operation, Conversion, Postoperative complications, Estimated Blood Loss, Length of Stay, Operating Time, Analgesia requirement, Cost
S – Study Design	• RCTs

	• Cohort Studies • Case Series reporting 10 or more patients

Data extraction

The extracted data will be collated in a data sheet. The full details of the data extraction fields and outcomes we will extract, where possible, are given in Supplementary File 2. Our key outcomes of interest are numerous, including operative success (i.e. procedures not requiring reoperation), length of stay, stent indwelling time, cost, estimated blood loss and complications. Our complications of interest include but are not limited to postoperative pain, subsequent haematuria or Urinary Tract Infection, stent dislodgement and pyelonephritis. We will also extract data regarding complications as classified by the Clavien-Dindo criteria, if given.

Data will be extracted by a minimum of one reviewer (PN, NC, AC) with any disagreements resolved by discussion. Relevant figures will be extracted from the data. If these are not provided, attempts will be made to calculate them from provided data. If this is not possible, the corresponding authors of each paper will be contacted to provide the relevant data. For studies not provided in English, an English language copy will be sought. If this is not successful, the authors will be contacted directly to obtain a translated version.

Risk of bias in individual studies

To assess bias and quality of the included studies a Newcastle-Ottawa score will be used, designed to assess the risk of bias in non-randomised studies [8]. This scoring system is split into three main sections: selection, comparability, and outcome. Each of the sections contains sub-questions that assess the quality of the research methodology, at the study level. For any

identified Randomised Controlled Trials (RCTs), version 2 of the Cochrane Risk of Bias tool for Randomised Trials will be utilised instead [9]. Three of the reviewers (PN, AC and NC) will be involved with this process, and any disagreement will be solved by consensus. These results of the risk of bias assessment will be utilised to carry out a sensitivity analysis, excluding studies deemed to be at a high risk of bias.

Meta-analysis

The nature of our research question means that three distinct comparisons will be made: open vs laparoscopic pyeloplasty, laparoscopic vs robotic pyeloplasty and open vs robotic pyeloplasty. As such, three meta-analyses will be conducted for each outcome of interest, given sufficient homogeneity in identified studies' reported outcomes. We will extract the raw numbers of each relevant outcome in both groups. Odds Ratios (for binary outcomes) or standardised mean differences (SMDs; for continuous outcomes) will be calculated and pooled. Between study heterogeneity will be assessed using τ^2 , Higgins and Thompsons I^2 statistic and Cochran's Q. Given significant between-study heterogeneity, a random-effects model with the Knapp-Hartung (KH) adjustment will be used to calculate a pooled effect measure using the generic inverse-variance method. Otherwise, a fixed-effects model using the exact Mantel-Haenszel method will be utilised. τ^2 will be calculated using the Paule-Mandel or restricted maximum likelihood estimator (REML) methods for binary or continuous outcome data respectively.

For studies with only one experimental group, proportions of each outcome of interest will be extracted and a meta-analysis of proportions carried out as per Wang et al. if more than three studies report sufficiently homogenous outcomes in this manner [10]. Proportions will first undergo logit transformation before being pooled using the generalised linear mixed-effects

model (GLMM), with the KH adjustment applied. τ^2 will be obtained using the maximum-likelihood estimator. Studies with three experimental groups will be split into two separate 'arms' and their respective proportions of each outcome extracted, with the sample size of the control group halved in order to attribute half the weighting to each study. The validity of this assumption and impact on pooled proportions will be tested in a sensitivity analysis.

For each meta-analysis, identification of outliers and influencer analysis will be undertaken if there is deemed to be significant between-study heterogeneity. Influencer analysis will take place in according to the Leave-One-Out method. Influential studies will be identified using a random-effects model. Influencer analysis will be visualised using a Baujat plot and plots of Influence Diagnostics (including externally standardised residuals, DFFFITS value, Cook's distance, Covariance ratio, Leave-One-Out τ^2 and Q values, hat values and study weights). Overall effect and I^2 will be visualised in forest plots. Outliers and influential studies will be excluded from the meta-analysis as part of a sensitivity analysis. Publication bias will be assessed using funnel plots. Given sufficient homogeneity of reported outcomes and enough studies reporting outcomes on infants (children <1 year of age), a subgroup analysis will be undertaken to identify any differences in outcomes between infants and children over 1 year of age.

Data cleaning and visualisation will be undertaken in R using the tidyverse, dplyr and ggplot packages. Meta analyses will be conducted in R using the meta package in accordance with Harrer et al [11]. If there is insufficient data to conduct a meta-analysis, only thematic synthesis will be performed.

Patient and public involvement

The public and patients were not involved in the development of this systematic review and meta-analysis protocol.

Discussion

Dismembered pyeloplasty remains the gold standard of treatment of patients with PUJO [12]. However, the optimal method of surgical access has not yet been determined based on key postoperative outcomes [13]. Given the relatively recent development of RALP, This triplicate comparison has not been evaluated in the literature yet [2]. Our review seeks to provide a comprehensive overview of the literature surrounding the three approaches to an Anderson-Hynes dismembered pyeloplasty, and evaluate their efficacy both in isolation and when compared against each other on the basis of key postoperative outcomes.

The importance of this comparison cannot be understated. Determining the standard of care is a monumental undertaking, especially when the significant costs associated with robotic surgery (both in its undertaking and in the training of surgeons) are considered. For example, the standard of care for children with PUJO is a RALP in the UK; however, this is not yet the case in less affluent nations [3]. If children undergoing RALP for PUJO are demonstrated to experience definitively better outcomes than children undergoing laparoscopic or open pyeloplasty, then children from poorer nations face worse surgical outcomes on the basis of their socioeconomic status. If, however, RALP is demonstrated to have similar or identical outcomes to open and laparoscopic techniques, then the additional cost of the procedure is made negligible [14]. A decision to switch to a more expensive procedure cannot be made without careful comparisons between the three groups, which our paper aims to highlight.

In the coming years we are likely to see a rise in the number of RALPs performed in children around the world, and as such, we should aim to better understand the indications and outcomes of this procedure in children. Through systematic review and meta-analysis we aim to identify commonality between studies that have investigated the outcomes of RALP and compared it to open or laparoscopic pyeloplasty.

Trial status

Preliminary searches: started.

Piloting of the study selection process: started.

Formal screening: started.

Data extraction: not started.

Risk of bias assessment: not started.

Data analysis: not started.

Draft of search strategy for MEDLINE, EMBASE, PubMed and Cochrane databases

(pyeloplasty) AND ((laparoscopic) OR (robotic) OR (open)) AND ((Ureteropelvic junction obstruction) OR (pelviureteric junction obstruction)) AND ((child) OR (p?ediatric)) AND (outcome)

Ethics Statement

Due to the nature of the present study, no relevant ethical concerns or informed consent will be required. The protocol and systematic review and meta-analysis will be disseminated through publication in a peer reviewed journal.

Author statement

PN, ID, JMN, SB and NZ contributed to the conception of the study. The manuscript protocol was drafted by PN, and was revised by AC, NZ, JMN, NC, EK and IA. NZ will arbitrate the disagreements and ensure that no errors are introduced during the study. All authors approved the publication of the protocol. PN is the guarantor of the review.

Data availability statement

No public dataset was used in the creation of this manuscript. Upon publication of the final systematic review, statistical code for the meta-analysis will be made available.

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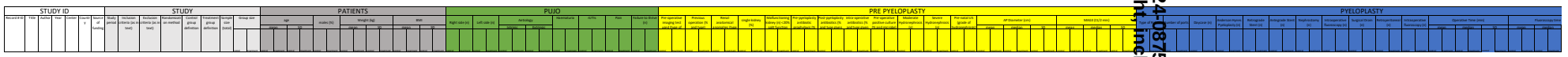

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	3
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1

Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	12
Amendments			
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support			
Sources	#5a	Indicate sources of financial or other support for the review	2
Sponsor	#5b	Provide name for the review funder and / or sponsor	N/A
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	5
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5, 7
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6, 7
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6, 7
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6

Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	S1
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