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Paediatric Surgical Outcomes Across Ontario

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Surgery

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ABSTRACT

BACKGROUND: The purpose of this study was to determine the volume of two complex paediatric procedures at the tertiary care centres in Ontario over the last 20 years in two disciplines, analyze outcomes and explore the possibility of an outcome volume relationship.

METHODS: A population based cohort study of patients undergoing TEF repair and pyeloplasty at 4 paediatric centres in Ontario between 1993 and 2013 was carried out. Administrative data sets were linked using unique encoded identifiers and analyzed at the Institute for Clinical Evaluative Sciences (ICES).

RESULTS: In TEF repair and pyeloplasty, there was significant difference in hospital volume between institutions and no significant difference in main outcome—reoperation rate between them.

CONCLUSIONS: This study demonstrated that although the institutional volume and surgeon volume is different, the reoperation rate between institutions is similar in tertiary paediatric Ontario centres.

Keywords

Outcomes

Volume

Tracheoesophageal Fistula

Ureteropelvic Junction Obstruction

Pyeloplasty

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I would like to acknowledge the contributions of Andrew McClure ³ and Jennifer Winick-Ng ³ (Institute for Clinical Evaluative Sciences, London, ON) who were involved in the study design, programming and data collection and analysis.

This study was supported by the Children's Health Foundation, London Health Sciences

Centre, London Ontario.

Acknowledgments

I thank my supervisor and mentor, Dr. Jones for help, patience and guidance.

I would like to thank my wife Krysia for her love and support.

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List of Abbreviations

CCI	Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures
CCP	Canadian Classification of Health Interventions
CHEO	Children's Hospital of Eastern Ontario
CIHI	Canadian Institute for Health Information
DAD	Discharge Abstract Database
DJ	Double J Stent
EA	Esophageal Atresia
GERD	Gastroesophageal Reflux
GS	General Surgeon
HDH	Hotel Dieu Hospital in Kingston
ICD-9	International Classification of Diseases, Ninth Revision
ICD-10	International Classification of Diseases, Tenth Revision
ICES	Institute for Clinical Evaluative Sciences
KGH	Kingston General Hospital
MIS	Minimal Invasive Surgery

NR	Non-reportable
LOS	Length of Stay
LP	Laparoscopic Procedure
OHIP	Ontario Health Insurance Plan
OP	Open Procedure
POP	Population and Demographics Database
PS	Paediatric Surgeon
RPDB	Registered Persons Database
RPG	Retrograde Pyelography
SD	Standard Deviation
SDS	Same Day Surgery
TEF	Tracheoesophageal Fistula
UGI	Upper Gastrointestinal Study
UPJ	Ureteropelvic Junction
UPJO	Ureteropelvic Junction Obstruction
VUR	Vesicoureteral Reflux

Paediatric Surgical Outcomes Across Ontario

1.1. Background

The outcome of surgical procedures are linked to a number of factors- these may include but are not exclusively limited to the clinical condition of the patient, the pre, post and inter-operative care, the complexity of the surgical procedure and the experience of the surgeon. Over the past few decades, many studies, across a variety of surgical procedures have shown that the outcomes of certain surgical procedures are related to the volume of operations performed at the centre. Simply put, patients treated in hospitals performing fewer operations are more likely to have complications [1-5].

The question remains as to why this is the case and a number of theories have been suggested. Hospitals performing more surgeries have not only more experienced surgeons, but also highly qualified, more experienced teams and broader range of resources [6]. There is also more likely to be a standardised care pathway in bigger centres, a concept known to be associated with better outcomes [7-9]. These higher volume hospitals then become known as “centres of excellence” and the referral pattern migrates towards these centres [10, 11].

A systematic review and methodological critique of the relationship between surgical volume and outcome by Ethan et al looked at 135 studies over the last twenty years [1]. They showed that overall 71% of these studies revealed a positive association between outcomes, hospital volume and individual surgeon volume. A positive relationship between hospital volume and outcome was reported in 44% of articles with no risk adjustment, this increased to 82% with risk adjustment based on administrative data and to 50% with risk adjustment based on clinical data. A positive association between physician volume and outcome was found in 62% studies with no risk adjustment, 68% with adjustment based on administrative data and to 73% using clinical risk-adjustment models. A larger systematic review from 2005 [12] showed that amongst 313 studies, 68% found a positive relationship between hospital and physician volume and outcomes, but the remaining 32% showed no significant difference. One percent of the studies (4 of 3143) showed a significant association between higher volumes and

poorer outcomes [11, 13, 14]. Wade et al., [13] demonstrated a better outcome following a Whipples procedure that were carried out at lower volume hospitals and a higher thirty-day mortality rate in higher volume centers. Similarly Luft et al., looked at 17 different surgically treated conditions in one million patients in over 900 hospitals. In two of his analysis the higher volume hospitals had higher mortality rates in patients with subarachnoid haemorrhage and patients with acute appendicitis. [11]. This finding of a few discrepant results may be explained on the basis of random error, since the probability that a typical analysis will produce a statistically significant result by chance alone (when truly is no difference) is approximately 5% [11].

The relationship between surgical volume and outcome has been mostly studied in patients undergoing complex abdominal, vascular and cardiac procedures in the United States [1, 12, 15, 16]. One of the first studies to be done in Canada was in 1995 on coronary artery bypass surgery, and it showed no volume-outcome effect [17]. Later Canadian studies showed positive relation between volume and outcomes with better results in centres with higher volume [18-21]. However at the same time many other Canadian studies on various procedures showed no relation between patient volume and outcomes [21-27].

The majority of outcome studies have looked at procedures that are relatively high risk, such as cardiac surgeries and vascular surgeries, and in the elderly adult population. It is difficult to ensure that the comorbidities between the populations studied are the same and the complexity of the surgical procedure itself is truly identical [28]. Most of the studies are carried out in singles centres and it is very difficult to compare them as they are done at different times (years), by different kinds of teams (academic versus non-academic) and as mentioned earlier the complexity of each surgery may not be the same [29-32]. Furthermore many of the studies are heterogeneous reporting a combination of hospital volume [18, 21, 22, 33], and total surgeon volume or individual surgeon volume [3, 20, 27, 34].

The influence of volume on outcomes in paediatric surgery procedures has been even less studied than in adult surgery. There is much less data, fewer patients, paediatric

specific centres and paediatric surgeons. In contrast the scope of paediatric surgery is large varying between procedures that are common and simple, such as inguinal hernia repair, to those that are rare and very complex associated with congenital defects. Up until the early 90's paediatric surgery in Canada was distributed among both community and tertiary care hospitals. There were many community physicians that performed a variety of both paediatric and adult procedures. Although the paediatric population has remained stable, the way in which paediatric surgical care is provided has changed. The infra-structure, the skills of the anaesthetist, the pre and post nursing care of the patients has become more complex. As a consequence most paediatric surgical procedures, certainly those in patients less than 1-2 years of age, or older with complex care needs are now performed in the 17 tertiary academic hospitals across Canada. Despite this consolidation the number of complex procedures at each tertiary care centre can remain quite low and some paediatric services such as paediatric cardiac surgery only occur in 5 centres in Canada.

Most of the paediatric volume outcome studies reported to date are from the US, are difficult to interpret and do not apply to the Canadian landscape. The studies combine data from paediatric procedures carried out in both adult and paediatric centres. For example a recent study by Salazar et al., [35] in the US looked at mortality following all surgical procedures carried out in 173 hospitals and in over 236,000 paediatric cases within 4 year time frame (2006-2010) and found a significant difference in mortality between lower and higher volume centres, in favour of the high-volume centres. However, authors noticed that 2/3 (67.7%) of outlier hospitals, were not specialized paediatric centres, which was certainly a confounder in the analysis of the data and confirms the need for comparison of similar paediatric institutions. A study by Chen et al., showed that both paediatric (PS) and adult general surgeons (GS), who performed greater than 37 paediatric cholecystectomies per year had better outcomes than those who performed fewer than 37 cholecystectomies per year (complication rate:13% vs. 15%, length of stay 2.3 vs. 2.6 days and lower costs: \$7761 vs. \$9462) [34]. There was no difference between paediatric and adult surgeons performing that procedure (GS vs. PS: complication rate: 14.9 vs. 15.6, LOS-2.5 vs. 2.5 days and costs-\$9055 vs.\$9484)[34]. However this is not a complex paediatric surgical procedure and is certainly not exclusive

to the domain of the specialty trained paediatric surgeon. Similar results have been obtained for the surgical procedures of pyloromyotomy and appendectomy [36-38]. Two Canadian studies have reported volume outcome results in studies that looked at the effect of subspecialty training on the outcomes following pyloromyotomy [38] and hernia repair [39]. Pyloromyotomy is a procedure that used to be performed routinely in community hospitals but over time has become consolidated, for the most part to the tertiary care centres in Canada. Langer et al., reported that 67.9% of patients were operated on by paediatric surgeons and 32% by general surgeons. The general surgeons had a complication rate 4 times that of the paediatric surgeon and sub analysis suggested that in both the general surgeon and the paediatric surgeon higher volumes resulted in better outcomes [38]. Similarly in the study by Bernstein et al., the rate of recurrent inguinal hernias was higher in the general surgeon group compared with the paediatric surgeon. There was an inverse correlation between surgeon volume and reoccurrence risk among the general surgeons [39]. Both the US and Canadian studies support the consolidation of paediatric care to paediatric specific centres.

Unlike the adult volume outcome literature and with the exception of the paediatric cardiac literature [16, 40] there is no data that compares the volume outcome relationship for the complex paediatric surgical procedures that are only carried out at specific paediatric centres. In Canada due to the small volume of paediatric cardiac procedures care is consolidated to only a few childrens hospitals. As yet this consolidation has not been applied to other complex paediatric procedures e.g. trachea-esophageal fistula repair. There are a number of issues associated with delivering paediatric surgical care in a limited number of locations. First one has to consider the demographics of the patient. Many patients would have to travel even further to receive care, the patient and primary care giver would be separated from the family unit for potentially a protracted length of time. Second the centralization of surgical care will impact other areas that provide support to the surgical patients, such as the paediatric critical care units and other specialized services. Furthermore the development of new or expansion of existing structures would be very costly.

It is important to evaluate the association of centre volume with the outcomes of

surgical procedures in children undergoing procedures at different centers in Canada. First it is necessary to determine if a relationship between volume and the outcome of a number of complex paediatric procedures does exist. A clearer understanding of the relationship may have a significant impact on strategies for improving clinical care, such as consolidation of services to a few centres in Ontario or Canada or maybe a more consistent approach to pre- operative evaluation of the patient and post –operative care.

Ontario is the most populated province in Canada with a paediatric population of 2.2 million with 142.000 births per year [41, 42]. It is acknowledged that most medical in hospital care of the children in Ontario is provided in the community hospitals but surgical care is, for the majority concentrated to the 5 Paediatric Academic Health Centres situated in Southern Ontario (Hospital for Sick Children in Toronto (HSC), Children’s Hospital of Eastern Ontario in Ottawa (CHEO), McMaster Children’s Hospital in Hamilton, Children’s Hospital at London Health Sciences Centre in London, and Kingston General Hospital (KGH) and Hotel Dieu Hospital (HDH) in Kingston). All of these have highly sub-speciality-trained paediatric surgeons including paediatric surgeons (for the purpose of this study and according to the terminology of the Royal college of Physicians and Surgeons of Canada paediatric surgeon describes the paediatric general surgeon), paediatric urologists, neurosurgeons, ophthalmologists, orthopedic surgeons to name a few. All centres have experienced support staff and the infrastructure such as the paediatric critical care units, which are needed to provide the best care for the children of Ontario. There is also a current model of consolidation with paediatric surgical cardiac care regionalised to HSC and CHEO. Thus Ontario provides an excellent landscape to start to look at the volume outcome relationship in paediatric surgery in a meaningful manner.

1.2. Purpose

The purpose of this study was to determine the volume of the following three complex paediatric procedures at the tertiary care centres in Ontario over the last 20 years

- ii. Study the outcomes of the procedures
- ii. Explore the possibility of an outcome volume relationship both at the hospital volume level but also at the individual surgeon level. The

project will incorporate the use of the Institute for Clinical Evaluative Sciences (ICES) data sets, to identify the volume of a number of the predetermined complex surgical procedures Tracheoesophageal Fistula (TEF) repair and pyeloplasty and associated outcomes in the paediatric population.

1.3. Hypothesis

We hypothesise that there is no difference in outcomes in complex paediatric surgery procedures performed by sub-specialty trained surgeons in children's hospitals in Ontario, despite predicted differences in operative volume.

1.4. Methods

1.4.1. Study Design

A population based retrospective cohort study of all paediatric patients undergoing TEF repair and pyeloplasty at paediatric centres in Ontario (Hospital for Sick Children in Toronto Children's Hospital of Eastern Ontario in Ottawa, McMaster Children's Hospital in Hamilton, Children's Hospital of Western Ontario in London) between April 1st 1993 and March 31st 2013 was carried out. Kingston General Hospital and Hotel Dieu Hospital Kingston were excluded because the provision of paediatric tertiary care surgical service was limited for the duration of the study period. The province of Ontario, Canada has universal access to hospital care and these encounters are recorded in large population-based health care databases dating back to 1992. Administrative datasets were linked using unique, encoded identifies and analyzed at the Institute for Clinical Evaluative Sciences (ICES).

1.4.2. Procedures chosen

A retrospective cohort study of paediatric patients undergoing one of the following two surgical procedures was carried out. The procedures TEF repair and pyeloplasty were chosen based on the following criteria:

- a. Performed at all of the identified study sites.
- b. Considered a procedure that is complex (index procedure).

- c. Performed only by a paediatric subspecialty trained surgeon.
- d. The surgical technique has not changed significantly over the study period.
- e. Is associated with post-operative complications that reflect the outcome of the procedure.
- f. The co-morbidities of the patient do not impact the outcome of the surgical procedure.
- g. The procedure and complications could be identified in the data sets used in the study.
- h. Unlike the adult literature where an assignment of patient complexity such as the Charleston score can be applied there is no such risk adjustment for complexity in the paediatric literature. It is very difficult to exclude completely the effect of individual patient comorbidities on parameters such as hospital length and morbidity. For this reason we excluded these measures from our analysis.

1.4.3. Data Source

The province of Ontario, Canada has universal access to hospital care and these encounters are recorded in large population-based health care databases dating back to 1992. Administrative datasets were linked using unique, encoded identifiers and analyzed at the Institute for Clinical Evaluative Sciences (ICES) Western site, located in London, Ontario, Canada. The ICES is a not-for-profit research institute encompassing a community of research, data, clinical experts and a secure and accessible array of Ontario's health-related data. The Institute for Clinical Evaluative Sciences is able to anonymously link population-based health information at an individual patient level, using unique ICES identifiers that ensure the privacy and confidentiality of health information [43, 44]. For the purposes of this study ICES linked data from the following data bases Discharge Abstract Database (DAD), Same Day Surgery (SDS), Registered Persons Database (RPDB) and the Ontario Health Insurance Plan (OHIP). These data bases allowed the identification of procedure codes, diagnosis codes that were applicable to the study populations (see below for identification of study population) for the period of study. Diagnostic and procedural information for all hospitalizations and one-day procedures are recorded in the Canadian Institute for Health Information's (CIHI)

discharge abstract and same-day surgery databases. Diagnosis codes were obtained from the International Classification of Diseases, Ninth (ICD-9: 1979-2005) and Tenth Revision (ICD-10: 2001- present). Codes for the surgical procedures were obtained from the Canadian Classification of Health Interventions (CCP: 1978-2002) and Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures (CCI: 2002- present) codes. Patient characteristics and baseline demographics were obtained from the Population and Demographics database (POP).

1.4.4. Study Population

Data was collected for all patients who met the inclusion criteria (Appendix A) who underwent one of the 2 index procedures TEF or pyeloplasty in the 4 tertiary centres in Ontario for the last twenty years (1993-2013). Patients were excluded if they did not have the diagnosis of the congenital defect and met exclusion criteria (Appendix B). The cohort was stratified into four, five years block to observe trends over time: 1993-1997, 1998-2002, 2003-2007, 2008-2013. These two initial data sets built the primary cohort of patients that were then followed to study outcomes related to the surgery (Appendix C and D). The 4 centres were very comparable in that all centres performed the identified procedures on a regular basis by subspecialty trained paediatric surgeons and provided similar support for the pre and post-operative care of the patients.

1.4.5. Outcomes

1.4.5.1. Demographics/ Baseline variables

Demographic data and baseline variables (e.g. volume of surgeries per centre/per surgeon/ era) associated with each cohort were collected and varied according to each procedure. For example in the TEF cohort data was collected around age at time of procedure, length of hospital stay, sex rurality etc.

1.4.5.2. Primary Outcome

Primary outcomes were established for the 2 index procedures and reflected a reoperation similar to the primary procedure. For example in the case of pyeloplasty the primary outcome was redo pyeloplasty (evidence of a redo pyeloplasty within 2 years of the index event).

1.4.5.3. Secondary Outcomes

Secondary outcomes were chosen specifically to represent complications other than the primary outcome. For example in pyeloplasty the need for a ureteric stent insertion after the index procedure might reflect leakage or obstruction from the anastomosis of ureter to the pelvis of the kidney.

1.4.6. Analysis

Data were reported for the complete 20 year period, stratified by year and by centre. The centres are described as A, B, C or D for the purpose of anonymity. Privacy regulations do not allow the presentation of any groups with data points <6. Where possible, data were analyzed using standard summary statistics ANOVA for continuous variables, Kruskal-Wallis test and Chi square test (categorical variables). P value <0.05 was considered to represent a significant difference between data sets.

1.5. Data Presentation

The data presented in this thesis is described in a series of chapters. The data are complete for the procedures TEF and pyeloplasty.

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2.0. Tracheoesophageal Fistula repair in Ontario over the last 20 years: how did we do?

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Key Words

Tracheoesophageal fistula repair

Outcomes

Volume

2.1. Background

Esophageal Atresia (EA) is a congenital condition in which there is a disruption in the continuity of the esophagus (Fig. 1). Esophageal atresia can occur in isolation or with a connection, known as a fistula to the trachea (tracheoesophageal fistula (TEF: Fig. 1).

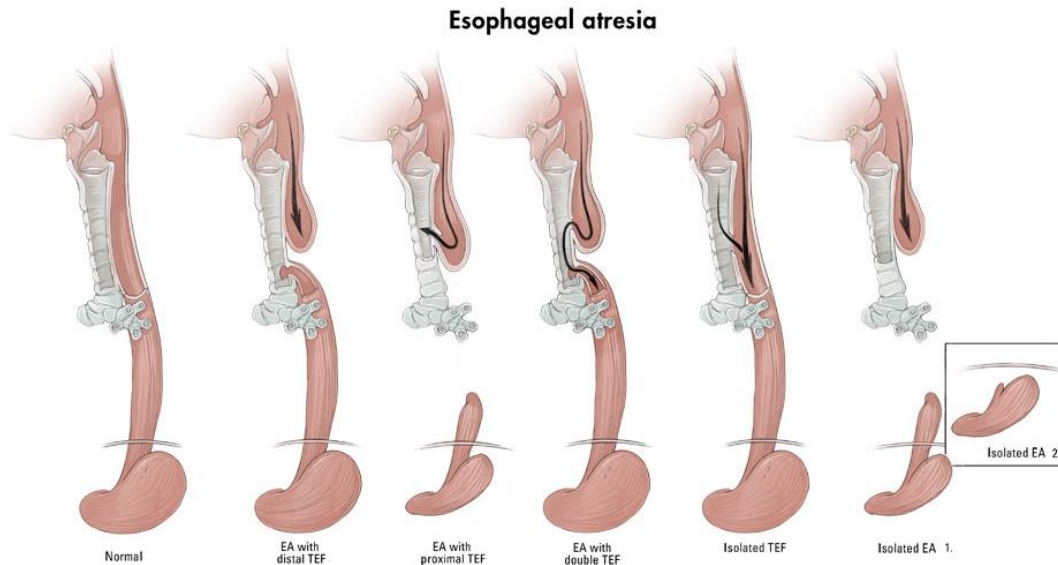


Figure 1. The Gross classification of esophageal atresia.

The anomaly results from an insult occurring within the fourth week of gestation, during which time separation of the trachea and esophagus usually occurs by folding of the primitive foregut [1,2]. Most cases occur sporadically without evidence of either hereditary or specific environmental teratogenic causes [3,4,5]. The incidence of EA/TEF varies between 2.55 and 2.82 per 10,000 births [3,4,5]. Esophageal atresia and TEF present in many forms and it should be thought of as a spectrum of anomalies. There are five main anatomic variants: EA with distal TEF (85%), pure EA (7%) known as a long gap, EA with proximal TEF (1%), EA with proximal and distal TEF (1%) and H-type fistula without EA (4%). The most frequently used classification was proposed by Gross in 1953 (Fig.1) [6].

The early disturbance in organogenesis causing EA/TEF may affect the organogenesis of other organs or systems developing at the same time. The most frequent associated malformations encountered with EA are: Cardiac (13%-34%), Vertebral (6%-21%), Limb (5%-19%), Anorectal (10%-16%) and Renal (5%-14%) [4, 5, 7]. The constellation of these anomalies is known as the VACTERL association (V= vertebral anomalies, A=anorectal malformations, C=Cardiovascular anomalies, T=tracheoesophageal fistula, E=esophageal atresia, R=renal anomalies or radial anomalies and L=limb defects). Mortality among babies with the VACTERL association is not insignificant but is not related to the EA/TEF but more to other identified prognostic factors such chromosomal abnormalities, major cardiac anomalies, renal anomalies, weight less than 1500g and gestational age <28 weeks. [8-13]. Thus although coincident anomalies may affect 40-60% of patients, it seems that EA/TEF is not a significant factor for these patients' mortality [14-16].

Surgical correction of TEF has been performed since 1941 [17] via a postero-lateral thoracotomy using an extra-pleural approach in most cases. Since 1943 when the first report was published the procedure itself has essentially remained unchanged [18] until Bax and van der Zee in 2002 reported their experience using thoracoscopy for EA and TEF repair [19,20].

The pitfalls of the operation, the incidence of complications and the outcomes, both short term and long term, have been reported by many paediatric surgeons around the world. However it is important to note that most of the studies are retrospective single centre chart reviews [14, 21-26]. Complications specifically related to the surgical procedure include early esophageal anastomotic leak, stricture and recurrence of TEF. Anastomotic leaks are reported to occur in 8-16% of cases and most of them are treated conservatively [27-30]. Esophageal strictures are very common 4-80% [23, 24, 27, 30-33] and most of them respond to dilatations [33, 34]. Recurrent TEF occurs in 3-14% of patients after the initial operation [15, 23-28, 35]. Patients who have undergone a TEF repair will often have associated dysphagia 20-40% [32, 36-38], gastroesophageal reflux (GERD) (27-85 %) [36, 39-41] or tracheomalachia (16-33%) [23,42-44]. The treatment of those conditions are variable, occasionally surgical intervention is required, such as a

fundoplication in the face of severe reflux but often conservative non-operative measurements are successful [21,23,37-39,42].

The relationship between volume of surgical procedures and surgical outcome has been broadly studied in the adult literature [45]. The results trend towards a positive relation between volume and outcomes, but there are also studies that suggest minimal effect. There are only few studies in paediatric surgery that have examined the volume outcome relationship and most of these are in paediatric cardiac surgery [46]. Of the few that have looked at non-cardiac procedures most of them have determined outcomes related to mortality only [47, 48] or to the specific training of the surgeon. Results are further confounded by the inclusion of data from those procedures carried out in children's hospitals alone and those from combined adult/ children's centres [49-51]. For example a large study by Shawn et al., reported that the outcomes of patients undergoing pyloromyotomy for hypertrophic pyloric stenosis were better in patients who were treated by a specialty trained paediatric surgeon compared to a general surgeon [12,49]. The purpose of this study was first to determine the number of TEF repairs in Ontario over the last 20 years and second to evaluate the association of centre volume/surgeon volume with post-operative complications in children undergoing TEF repair, utilizing data from well-established province-wide healthcare databases held at the Institute for Clinical Evaluative Sciences (ICES)

2.2. Patients and Methods

2.2.1. Study Design

A population based retrospective cohort study of all paediatric patients undergoing TEF repair at 4 paediatric centres in Ontario (Hospital for Sick Children in Toronto (HSC), Children's Hospital of Eastern Ontario in Ottawa (CHEO), McMaster Children's Hospital in Hamilton, Children's Hospital of Western Ontario in London) between April 1st 1993 and March 31st 2013 was carried out. The province of Ontario, Canada has universal access to hospital care and these encounters are recorded in large population-based health care databases dating back to 1988. Administrative datasets were

linked using unique, encoded identifies and analyzed at the Institute for Clinical Evaluative Sciences (ICES).

2.2.2. Data Sources

Diagnostic and procedural information for all hospitalizations and one day procedures were obtained from the Canadian Institute for Health Information's (CIHI) discharge abstract (DAD), same day surgery (SDS) databases and Ontario Health Insurance Plan (OHIP). Patient characteristics and baseline demographics were obtained from the Registered Persons Database (RPDB). Data Cases were identified using codes of TEF from International Classification of Diseases, Ninth and Tenth Revision (ICD-9 until 2002 and ICD-10 since April 1, 2002 for discharge diagnoses (up to 16 fields) and procedure codes for TEF surgical repair procedures using the Canadian Classification of Health Interventions (CCI) until 2002 and Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures (CCI) 2002 onwards. These databases hold approximately 53350 codes that describe procedure and diagnosis codes. Specific codes were used to identify the initial cohort and then the primary and secondary outcomes associated with TEF repair. The number of specialty trained paediatric surgeons at each Institution for the period of study was obtain by personal communication (Dr. S. Jones)

2.2.3. Cohort Build

All patients undergoing a primary TEF repair (index procedure) between April 1st 1993 and March 31st 2013 at the following 4 paediatric centres in Ontario, Canada were identified. Data were abstracted from the time of the index procedure until two years of follow up or until death. All paediatric patients resident in Ontario aged 180 days or younger who were Ontario residents when the index (initial TEF repair) procedure was performed were included in the study. Patients were excluded if they were not registered in ICES, older than 180 days, not residents of Ontario, died before the index procedure, that were not operated on in the one 4 paediatric teaching centres (see paragraph 2.2.1.) and patients who had the procedure done because of other, non-congenital diagnosis (e.g.

injury or malignancy). Eight hundred and twenty five underwent tracheoesophageal fistula repair during the last 20 years in Ontario, after excluding criteria were applied 465 paediatric patients remained in the cohort (Table 1).

Step	Number excluded	Number included
Original cohort	Before Exclusion	825
Missing sex or age	9	816
Death prior to index date	0	816
Age >= 180 days	322	suppressed
Non-Ontario resident	NR (included in step below)	suppressed
No diagnosis of TEF 60 days prior to index da	NR (included in step below)	suppressed
Procedure not performed at pediatric teaching	NR (included in step below)	suppressed
Evidence of other esophageal injury	29	465

Table 1. TEF cohort build. 825 patients underwent TEF repair; after excluding adult patients and that who had this procedure done, but not associated with the diagnosis of congenital TEF, 465 newborns who had TEF repair in Ontario in the last 20 years remained in the cohort.

The cohort was stratified into four, five years block to observe trends over time: 1993-1997, 1998-2002, 2003-2007, 2008-2013. We analyzed outcomes up to two years after the index surgery. Patients were excluded if sex or date of birth were missing, if death occurred prior to the index event, or if there was no diagnosis of TEF associated with the hospital discharge date within 60-days prior to the index procedure (including the procedure date) in DAD or SDS. Patients were also excluded if the encounter was associated with evidence of other esophageal injury or malignancy within 60-days before the index date (including the index date) in DAD or SDS.

2.2.4. Outcome

The primary outcome was reoperation of TEF repair and or surgery for definitive reconstruction of the esophagus (gastric pull-up or intestinal pull-up). Secondary

outcomes were identified as: other surgical procedures of the bronchus, trachea and esophagus, insertion of a gastrostomy tube, the procedure of dilatation of esophageal stricture, assessment of esophageal patency /motility/GERD by radiological contrast study (upper gastrointestinal study (UGI)) and “other” surgical interventions that occurred related to the TEF repair.

2.2.5. Analysis

Data is reported for the complete 20 year period, stratified by year and by centre. The centres are described by the A, B, C or D for the purpose of anonymity. Privacy regulations do not allow the presentation of any groups with data points <6, these are indicated by NR in tables. Where possible, data were analyzed using standard summary statistics ANOVA for continuous variables, Kruskal-Wallis test and Chi square test (categorical variables). P value <0.05 was considered to represent a significant difference between data sets.

2.3. Results

2.3.1. Patient and Centre Characteristics

A total of 465 patients from the 4 centres met the criteria for inclusion in the primary cohort (both diagnosis of TEF and procedures of TEF repair: Table 1).

Code	Description of code	Frequency
1GJ86ME	Closure of fistula, trachea open approach for fistula terminating at esophagus [e.g. tracheoesophageal fistula] with simple apposition for closure [e.g. suture]	48
1GJ86MEXXE	Closure of fistula, trachea open approach for fistula terminating at esophagus [e.g. tracheoesophageal fistula] using local flap [e.g. strap muscle]	9
1NA84QE	Construction or reconstruction, esophagus with tracheoesophageal fistula repair Open thoracic approach	178
1NA84QJ	Construction or reconstruction, esophagus with tracheoesophageal fistula repair Open thoraco-abdominal approach	12
4363	Closure of other fistula of the trachea	202
5441	Esophagoesophagostomy	16

Table 1A. Distribution of patients undergoing primary tracheoesophageal fistula repair identified by the procedure codes (CCP and CCI).

As expected all primary procedures were completed as an inpatient. Of the primary cohort 41.5% of patients were females and 58.5% were males. The mean age of the index surgery was 7.7 days (SD 21.49) and there was no significant difference in age of primary operation between institutions (Table 2).

	All		Age of patients undergoing TEF repair (index procedure) by institution								p-value (from ANOVA)
	Mean	SD	A		B		C		D		
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Patient age (days)	7.7	21.49	6.64	24.41	5.18	12.14	8.78	21.47	7.44	24.77	≥ 0.05

Table 2. Age distribution of patients at time of index tracheoesophageal repair (TEF) repair (index procedure) between institutions shown for the institutions A, B, C and D.

The average number of primary TEF repairs was 23.25/year for the last 20 years (Fig. 2).

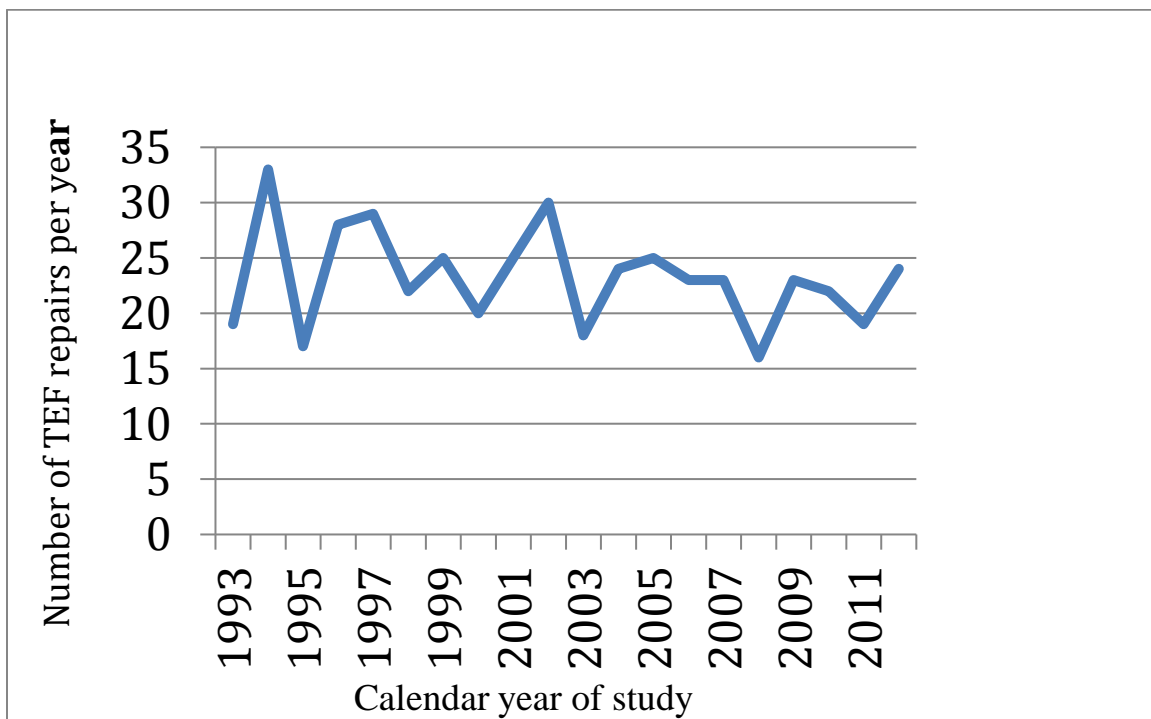


Figure 2. Number of tracheoesophageal fistula (TEF) repairs in Ontario over the last 20 years (1993-2012).

The number of TEF repairs for the eras: 1993-97, 1998-2002, 2003-2007 and 2008-2013 was 126, 122, 113 and 104 respectively (Fig. 3).

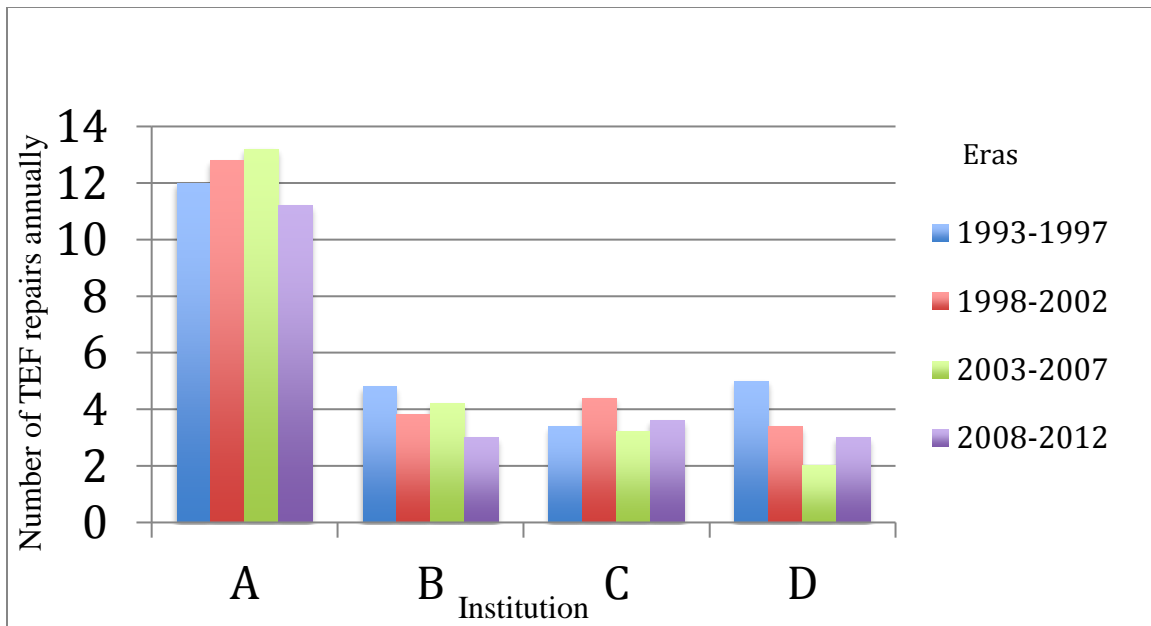


Figure 3. Mean number of tracheoesophageal fistula repairs (TEF) per institution A,B,C and D stratified by 4 time periods. To ensure anonymity of primary and secondary outcomes it is important to note that the identification assignment of the institutions in this figure is not carried through the remainder of the manuscript.

There is statistically significant difference in patient volume per institution (Table 3) for the 20 years of study.

	All		Number of TEF procedures per institution per year								p-value (from ANOVA)
	Mean	SD	A		B		C		D		
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Patient annual volume	5.8	4.41	3.95	2.01	3.65	1.42	3.35	2.85	12.3	2.74	<0.05

Table 3. Mean annual volume of primary tracheoesophageal fistula repairs (index procedure) per institution. To ensure anonymity of primary and secondary outcomes it is important to note that the identification assignment of the institutions in this table is not carried through the remainder of the manuscript.

The maximum number of primary TEF repairs per surgeon was 2.5/year and this has fallen with time to numbers that range from <1 to 1.5 cases per surgeon (Fig. 4).

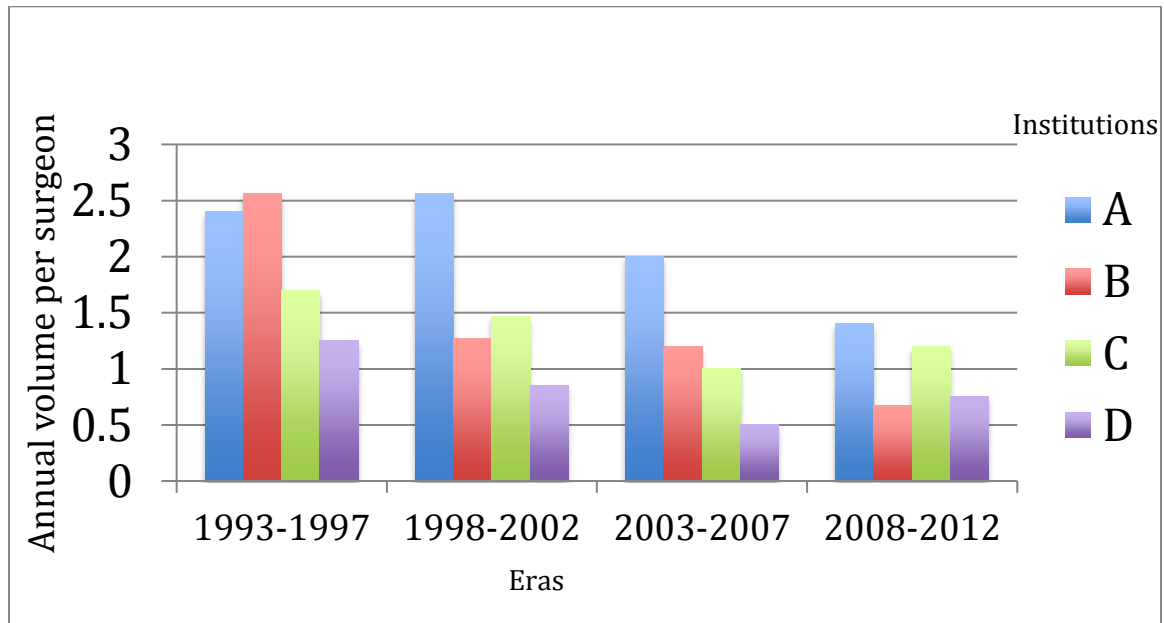


Figure 4. The average number of tracheoesophageal fistula repairs (TEF) repairs per surgeon at institutions A, B, C and D stratified by era. To ensure anonymity of primary and secondary outcomes it is important to note that the identification assignment of the institutions in this figure is not carried through the remainder of the manuscript.

2.3.2. Outcomes

2.3.2.1. Primary Outcomes

Five percent (n=25/465) of the primary cohort went on to require reoperation, 16 of them for recurrent fistula and 8 with intestinal interposition. Due to the very low numbers of patients undergoing a gastric pull up the site of the reoperations or pull up procedures cannot be identified (Table 4).

	All		Primary Outcomes at institutions				p-value
	No.	%	A	B	C	D	
			%	%	%	%	
Primary Outcome (Total)	25	5.3	not reportable				not reportable
TEF repair	16	3.4					not reportable
Gastric pull-up	not reportable						not reportable
Intestinal pull-up	8	1.7					not reportable

Table 4. The primary outcome of patients undergoing tracheoesophageal fistula (TEF) repair. Patients can contribute to more than one outcome component but can only occur once in the total number (composite number).

2.3.2.2. Secondary Outcomes

A gastrostomy tube was performed on 144 (31%) of TEF patients and ranged from 15-38% between institutions (Table 5).

	All		Secondary outcomes at institutions				p-value
	N=	%	A	B	C	D	
			%	%	%	%	
Gastrostomy tube	144	31	27.4	28.4	37.8	15.2	<0.05
Esophageal dilatation	212	45.6	53.4	50.7	41.9	45.6	>=00.5
Upper GI study	126	27.1	27.4	31.3	22.8	36.7	>=00.5
Fundoplication	51	11	Not reportable				not reportable

Table 5. Number of secondary outcomes in patients having undergone a tracheoesophageal fistula repair by institution.

Dilatation for oesophageal stricture was reported in 45.6% of TEF patients (range 41.9-53.4% between institutions). An upper GI study was performed in (27.1% patients and ranged between 22.8-36.7% between institutions (Table 5). As expected the number of surgical procedures of the bronchus after primary TEF repair was very low (n=6) for the 20 years of study (Table 5A).

Other Surgical Interventions	All		Outcomes at institutions				p-value (from Chi-square test)
			A	B	C	D	
	Number of events	%	%	%	%	%	
Total number of interventions	206	44.3	53.4	52.2	41.1	39.2	≥ 0.05
Bronchus intervention	6	1.3	not reportable				not reportable
Mediastinal intervention	41	8.8	not reportable				not reportable
Tracheal intervention	92	19.8	21.9	23.9	17.5	21.5	≥ 0.05
Esophageal intervention	105	22.6	16.4	34.3	24	13.9	< 0.05
Thoracic duct intervention	not reportable	not reportable	not reportable				not reportable

Table 5A. Other Surgical Interventions. Different than reoperation, but related to bronchi, mediastinum, trachea, esophagus and thoracic duct.

19,8% of patients underwent 92 procedures that were identified under the general classification of tracheal procedures. These were most commonly minor thoracic interventions associated with pleural drainage e.g. drainage, pleura using percutaneous catheter (intercostal) with underwater seal drainage system or drainage, pleura using open approach and leaving drainage tube in situ, that occurred after the index procedure date (Table 5B).

Tracheal Interventions n=92			Esophageal Interventions n=105		
Code	Description	Frequency	Code	Description	Frequency
1GV52LATS	Drainage pleura using open approach and leaving drainage tube in situ	29	5475	Repair of esophageal stricture	44
1GV52HAHE	Drainage pleura using percutaneous catheter with underwater seal drainage system	24	5479	Other Repair of Esophagus	15
4396	Other operations on trachea	9	1NA80DBXXE	Repair, esophagus using local transposition flap, using endoscopic abdominal approach	8
			1NA80LBXXE	Repair, esophagus using local transposition flap, using open abdominal approach	8
			5474	Repair of other esophageal fistula	6

Table 5B. Tracheal and Esophageal Interventions codes.

There were many other codes that were identified to involve the trachea, but the numbers were too small to report on an individual basis (Table 6).

Code	Description	No.
1GJ86DAW3	Closure of fistula, trachea endoscopic approach for fistula terminating at esophagus [e.g. tracheoesophageal] with simple	<=5
1GV52HATK	Drainage, pleura using percutaneous catheter with suction pump, (under water seal or negative pressure)	<=5
1GJ54JATS	Management of internal device, trachea of tube (e.g. T-tube, drainage tube)	<=5
1GV52DATS	Drainage, pleura using endoscopic approach and leaving drainage tube in situ	<=5
1GJ50BANR	Dilation, trachea endoscopic approach using stent	<=5
1GJ80DA	Repair, trachea with simple apposition[e.g. suture] endoscopic (percutaneous) approach	<=5

Table 6. Examples of “Tracheal repair” codes that were used in such small number (<6) and therefore could not be reported.

There was no significant difference in the percentage of tracheal procedures between institutions (range 17.5-23.9%: $p>0.05\%$ from Chi-square test). A total of 22.6 % (range 13.9-34.3%: Fig. 5) of patients underwent an esophageal procedure. There was a statistical difference between institutions in other oesophageal repair (range 17.5-23.9%: $p<0.05\%$ from Chi-square test).

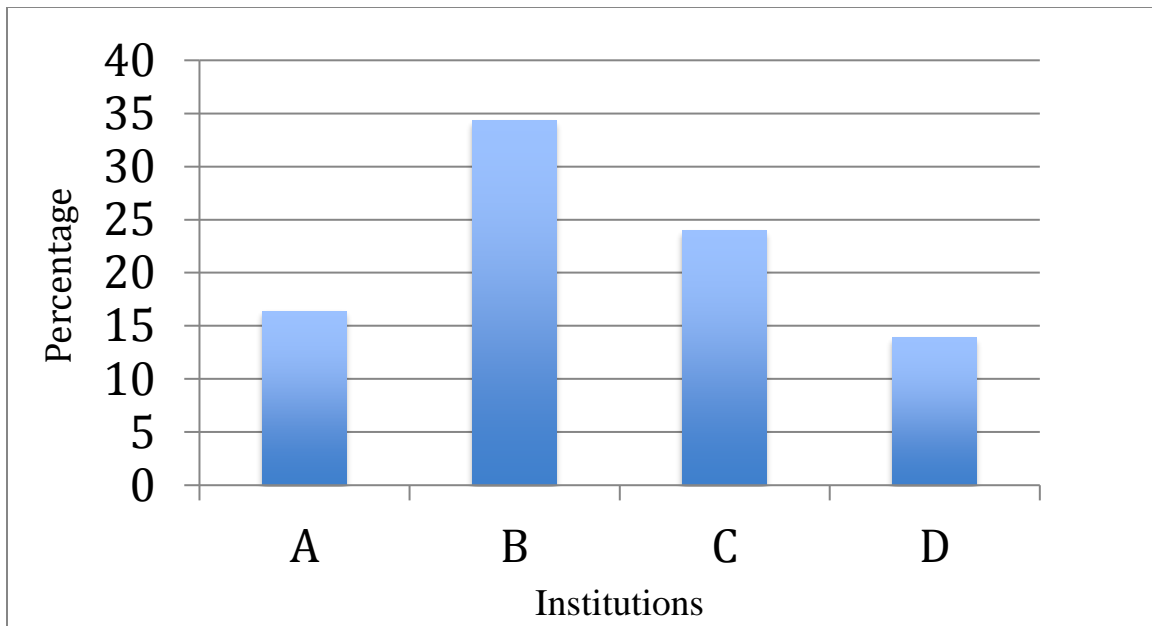


Figure 5. Percentage of other esophageal repairs at institutions A, B C, and D.

The majority of these interventions were related to repair of esophagus/esophageal stricture (n=105). It is difficult to interpret this data, it is likely that number of stricture repairs is overestimated as there was no CCP code that described an esophageal dilatation, just esophageal stricture repair. It is likely that during the first 10 years of the study the code for stricture repair was used to describe an esophageal dilatation. The remaining procedures were associated with codes that occurred in very small numbers, and were also related to repair of esophagus by flap etc. (Table 7).

Code	Description	No.
1NA80LB	Repair, esophagus using apposition technique [e.g. suturing] for closure using open abdominal approach [includes: cervical with abdominal approach, transhiatal approach]	<=5
1NA76QD	Bypass, esophagus thoracic approach [may include cervical with thoracic approach] Esophagoesophagostomy	<=5
1NA80BA	Repair, esophagus using apposition technique [e.g. suturing] for closure using endoscopic per orifice approach	<=5
1NA80QB	Repair, esophagus using apposition technique [e.g. suturing] for closure using open thoracic approach [includes: open cervicothoracic approach]	<=5
546	Esophagomyotomy	<=5
1NA77SQ	Bypass with exteriorization, esophagus using chest wall [subcutaneous] tunnel exteriorization technique	<=5

Table 7. Examples of “Esophageal repair” codes that were identified but that could not be reported due to small numbers.

Fundoplication for GERD was performed on 51 (11%) patients and the numbers are too small to report institutional distribution (Table 5). Insertion of a gastrostomy tube was performed in 31% of the total cohort of patients following TEF repair. There was a significant difference in insertion rate between institutions ranging from 15.2% to 37.7% ($p<0.05$).

2.4. Discussion

This is the first study of its kind, with the exception of paediatric cardiac surgery, that a complex paediatric surgical procedure has been used to investigate the relationship not only between surgical hospital volume and outcome but also describes the number of cases per surgeon. Tracheoesophageal fistula repair was chosen since it is a procedure that is associated with a surgical technique that really has not changed over the last 20 years, the period of data collection. Over the last 10 years there has been a shift towards the minimally invasive approach towards TEF repair but this has yet to be adopted widely within the province of Ontario and only over the last 5 years. Tracheoesophageal fistula

repair does occur with other congenital anomalies but the technical aspects of the outcomes of the repair itself for the most part are not affected by those anomalies. This study chose not to look at factors such as mortality and hospital stay which would be likely to be influenced by other factors than just the post-operative course related to TEF repair, especially if the patient had other significant co-morbidities such as complex heart disease. Rather outcomes were chosen that were specific to the repair of TEF, were accurately described in the data sets that were used and were commonly found in patients who had undergone TEF repair. We acknowledge we may have lost some patients in our primary outcome group as they may have died before going to redo TEF, but this number would likely be very small as the overall mortality inpatients undergoing TEF repair is very low [16,27].

The result of this study demonstrate that even in the province of Ontario with a birth rate of approximately 140,000 per year and with a data collection of 20 years it is still difficult to generate data on an index procedure with such a low occurrence as TEF. The results of this study suggest that the incidence of TEF in Ontario is consistent with previously published data [12, 27, 35, 52, 53] and that it decreased over the study period. This may be a result of antenatal diagnosis and termination of pregnancy in fetuses with other severe congenital anomalies in association with TEF.

Interestingly as the incidence of TEF has decreased the number of paediatric surgeons performing the repair has increased over time. In 1993 there were 13 subspecialty trained paediatric surgeons working in the 4 hospitals and this increased to 20 in 2013 (Dr. S. Jones personal communication). The data clearly shows that one centre in Ontario provides care to 50% of the patients in the province undergoing the primary TEF repair, with the remaining 50% being split approximately evenly between the other 3 centres. In contrast, when one considers individual surgeon volume the differences become minimal especially during the last era studied, 2008-20012, the volumes per surgeon are about 1 TEF repair per year. This is a very low volume and assumes there is no one particular surgeon that specializes in TEF repair at each centre. To the authors knowledge there is no such specialization in the centres studied. In fact in smaller, non-

teaching centers, is common practice to ensure that two surgeons are present for TEF repairs (Dr. S. Jones personal communication). Due to limitations in billing practise during the period of the study it would be impossible to accurately determine the number of surgeons attending a case. Of the 4 centres in Ontario, 3 have residency training programs, it is assumed, that all residents would attend TEF repairs and as such would have significantly greater exposure to cases per year than the individual primary surgeon. Although we have the approximate number of surgeons per era per institutions we do not have data on the specifics of each surgeon, for example how long they had been in practise and whether they worked pull or part time.

The primary outcome, recurrent TEF repair occurred in 3.4% of the primary cohort. This rate is at the lower end of values reported in the literature. The numbers reported for each centre were less than 6, suggesting that all centres contribute to the reoccurrence rate. We presume that the incidence of reoperation is very similar in all institutions as all pediatric surgeons in Ontario have very similar if not the same training and most of them use similar care pathways.

One of the complications associated with TEF repair is anastomotic leak. There is no coding that can be used to identify those cases but the placement of a pleural drainage device after the day of the index procedure might represent the non-operative, preferred, management of an esophageal leak. This occurred in approximately 10% of patients and is similar to rates reported in the literature. The rate of esophageal dilation was very consistent with reports in previous literature and very similar between institutions [52-54].

This study demonstrated that over 20 years in Ontario the complication rate associated with TEF repair is comparable with reported rates, if not lower. It also demonstrates that with the exception of repair/resection of stricture of esophagus stricture and insertion of gastrostomy tube all other outcomes are comparable between centres. It is beyond the limits of this study to identify the particular centre and the specifics of the esophageal procedures carried out in that centre. However these findings highlight the need for a future study when with a specific request the data can be further examined to

look at this complication. This analysis may then highlight differences in clinical practices such as of segmental resection of the esophagus versus continued dilatation or a different technique of dilatation.

Although this study is the first of its kind, to use population based data sets to look at TEF outcomes it has identified a number of limitations. Unfortunately the numbers of the index procedure are low and as was demonstrated when primary and secondary outcomes are also infrequent occurrences, the specifics of the outcomes in relation to site cannot be determined. In this study it may be of minimal significance as the rate of most of the outcomes was very low suggesting the overall success of the procedure is excellent. This study did not attempt to validate the codes used to identify the secondary outcomes and this would be an important step, for example, when investigating the centre specific difference in esophageal repair. These are limitations that are likely to apply to a significant number of the complex paediatric procedures and this highlights the difficulty in determining volume outcome relationships in the surgical paediatric population. Due to coding limitations this study was unable to address the influence that thoracoscopic TEF may have had on the primary and secondary outcomes.

In summary this study demonstrated that individual surgeons in Ontario perform approximately the same number of TEF repairs each year. The numbers of recurrent TEF repairs are very low and a therefore a volume outcome relationship cannot be determined. However this is actually reassuring, if the rate of recurrent TEF repair was high then a volume relationship could have been observed. The finding that there are differences in secondary outcomes will require further investigation.

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3.0. Pyeloplasty in Ontario over the last 20 years: how did we do?

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Key Words

Ureteropelvic junction obstruction

Pyeloplasty

Outcomes

Volume

3.1. Background

Ureteropelvic junction (UPJ) obstruction is a restriction in the flow of urine from the renal pelvis to the ureter. The physiologic compensatory response to ureteropelvic junction obstruction (UPJO) is the development of renal pelvic hypertrophy and hydronephrosis [1-3]. If left uncorrected, it may lead to changes in the renal pelvis, pressure-induced injury and consequently irreversible renal damage. The cause of obstruction is a narrowed segment of the proximal ureter at the UPJ and lack of peristalsis at the site of narrowing. The narrowing can be due to interruption of the circular musculature of the UPJ, valvular mucosal folds or lower pole crossing vessel [4-6]. Ureteropelvic junction obstruction coexists with severe vesicoureteral reflux (VUR) in about 10% of cases [7].

There are other congenital malformations, which are commonly associated with UPJO. Up to 10-50% of affected children may have other urologic abnormalities such as UPJO of the contralateral kidney, renal dysplasia and multicystic kidneys or unilateral renal agenesis [8, 9]. Bilateral UPJO is reported commonly in the literature (10-40%) and is most commonly associated with fetal or neonatal hydronephrosis [10, 11]. In many of these cases, the hydronephrosis normalizes after birth and UPJO requiring operative intervention is rare [13-15].

Various surgical procedures have been described for the treatment of UPJO in children, such as endopyelotomy or dismembered pyeloplasty - the excision of the affected proximal ureter fragment and then re-anastomosis. Pyeloplasty can be performed as an open procedure (OP) [16, 17], laparoscopically (LP) [18], or as a retroperitoneal [19] or transperitoneal [20] robot-assisted laparoscopic procedure [21, 22]. The dismembered Anderson-Hynes pyeloplasty has remained the gold standard for the treatment of UPJO since it was first described in the late 1940s, with success rates of more than 90% [23].

There are a few factors that have been reported to influence the surgical outcomes of pyeloplasty. Braga et al., 2010 [24] reported an increased reoperation rate amongst patients who were operated on by dorsal lumbotomy vs. lumbar approach (8.3 vs. 2.3%) and who did not have retrograde pyelography (RPG) (8.3 vs. 2.1 reoperation rate) [24,

25]. In many studies open pyeloplasty (OP) and laparoscopic pyeloplasty (LP) have shown comparable outcomes in terms of complications, but there are reports of differences in other variables such as length of stay [26-29]. Mei et al., in 2011 reviewed 1403 studies and found a decreased length of stay in patients undergoing a LP versus OP and no difference between the two procedures in terms of complication rate [26]. In 2015 Huang et al., again reported a shorter LOS but prolonged operative time and reduced complication rates in LP vs. OP. Another factor that influences the complications associated with pyeloplasty is the use of trans anastomotic stents during the operation. Some studies have shown that outcomes are not related to stent insertion during the procedure [28-30], while other reports show an advantage of using the stent (less incidence of leakage or cloth obstruction and shorter LOS) [27].

Paediatric pyeloplasty is a highly successful procedure. Success rates in excess of 90-98% are uniformly reported, regardless of the technique used to perform the procedure (open surgery, trans and retroperitoneal laparoscopy, or robotic-assisted) [16, 24, 31, 32]. Nevertheless, a 3%-10% failure rate has been consistently described in published reports [25, 33, 34] and the ideal approach to this small subset of patients with a failed pyeloplasty is yet to be determined.

The relationship between the volume of surgical procedures and surgical outcomes has been broadly studied in adult literature [35, 36]. Overall the results trend towards a positive relationship between volume and outcomes. There are few studies in paediatric surgery, especially in paediatric urology, that have examined this volume-outcome relationship. Currently most of the studies in the literature are from paediatric cardiac surgery [37] and most have determined outcomes related only to mortality [38, 39] or to the specific training of the surgeon [40, 41]. Results are often confounded by the combination of data from operations carried out at children's hospitals and combined adult/paediatric centres [40, 42, 43]. In paediatric urology there are few studies, which report outcomes of urological procedures performed by paediatric urologists. Wang et al., 2015, compared outcomes in paediatric urology (ureteral re-implant,

ureteroureterostomy, pyeloplasty, radical nephrectomy, partial nephrectomy, bladder extrophy repair, appendicovesicostomy, bladder augmentation, vesicostomy, bladder neck sling and percutaneous nephrolithotomy) and found a positive relation between hospital volume and outcomes [44]. Unfortunately this study included various types of hospitals: metropolitan teaching and nonteaching, and nonmetropolitan, and 75% of these hospitals performed less than 5 major paediatric urology operations annually. The study reported a higher volume of complications such as acute renal failure, urinary tract infection, postoperative respiratory complications, systemic sepsis, postoperative bleeding and in hospital death in the low volume centres [44]. Two other studies that looked at outcomes following ureteral reimplantation demonstrated a positive volume-outcome relationship with regards to surgeon volume but not hospital volume [45, 46]. Later, Nguyen et al., similarly demonstrated a positive volume-outcome relationship between surgeon volume and outcomes following ureteroneocystostomy [45]. In 2014 Sturm et al., demonstrated a positive, although minimal, influence of surgeon volume on outcomes [47]. One study demonstrated the positive influence of high hospital volume on pyeloplasty outcomes, although it demonstrated worse outcomes if the procedure was performed laparoscopically versus open in both high and low volume centres [48].

There are a few surgical complications that can occur following pyeloplasty: urinary tract or wound infection, postoperative bleeding (rare), postoperative leakage at the anastomotic site and recurrence of obstruction [16, 24, 25, 31-34, 49]. Most infections can be easily managed by antibiotics. Leakage can be treated by the insertion of a double J stent (DJ) or insertion of a nephrostomy tube. Success of the pyeloplasty is defined as improvement in hydronephrosis and stabilization or improvement in renal function.

Recurrence of obstruction is considered a late complication which requires surgical intervention ranging from minimally invasive endourologic procedures, such as stent insertion and endopyelotomy, to more extensive and challenging operations such as redo pyeloplasty and ureterocalicostomy [50]. A Canadian study by Braga et al., [51] reported a success rate of 39% with endopyelotomy compared to 100% following a redo pyeloplasty. Asensio et al., 2015 reported comparable outcomes, all be it in a small number of patients undergoing an open redo pyeloplasty versus a robotic assisted

pyeloplasty [33]. The result of laparoscopic redo pyeloplasties are also excellent (Abraham et al., 2015) [52]. A Canadian study by Romao et al., 2013, [50] showed a pyeloplasty failure rate of 5.9% in patients undergoing either an OP or LP. The failures were managed with success by DJ stent insertion (6%), endopyelotomy (50%), redo pyeloplasty (92%), and ureterocalicostomy (100%).

Most of above studies reported outcomes from single centres [16, 19, 21, 24, 25, 32, 51] or combined data from both adult and paediatric centres, and different urological procedures [17, 20, 26, 30, 31]. This makes it difficult to determine the effect on outcomes related specifically to either hospital or surgeon volume or specific procedure [44-48]. A study should be carried out that looks at outcomes between similar centres that provide the same operation on paediatric patients. The purpose of this study was to first determine the volume of pyeloplasties being carried out in Ontario and second to evaluate the association of centre volume and surgeon volume on post-operative complications in children undergoing pyeloplasty repair, utilizing data from well-established province-wide healthcare databases held at the Institute for Clinical Evaluative Sciences (ICES)

3.2. Patients and methods

3.2.1. Study Design

A population based retrospective cohort study of all paediatric patients undergoing pyeloplasty repair at 4 paediatric centres in Ontario (Hospital for Sick Children in Toronto (HSC), Children's Hospital of Eastern Ontario in Ottawa (CHEO), McMaster Children's Hospital in Hamilton, Children's Hospital of Western Ontario in London) between April 1st 1993 and March 31st 2013 was carried out. The province of Ontario, Canada has universal access to hospital care and these encounters are recorded in large population-based health care databases dating back to 1988. Administrative datasets were linked using unique, encoded identifiers and analyzed at the Institute for Clinical Evaluative Sciences (ICES).

3.2.2. Data Sources

Diagnostic and procedural information, length of stay and readmission to the hospital (within 21 days after the index procedure) for all hospitalizations and one day procedures were obtained from the Canadian Institute for Health Information's (CIHI) discharge abstract (DAD), same day surgery (SDS) databases. Patient characteristics and baseline demographics were obtained from the Registered Persons Database (RPDB). Cases were identified using discharge diagnosis codes (up to 16 fields) for UPJO from the International Classification of Diseases, Ninth and Tenth Revision (ICD-9 prior to 2002 and ICD-10 April 1, 2002- present) and procedure codes for pyeloplasty procedures using the Canadian Classification of Health Interventions (CCP: prior to 2002) and the Canadian Classification of Diagnostic, Therapeutic and Surgical Procedures (CCI: 2002 to present). Data was obtained via personal communication regarding the number of specialty trained paediatric surgeons at each institution for the period of the study (Dr. S. Dave)

3.2.3. Cohort Build

All patients undergoing a primary pyeloplasty (index procedure) between April 1st 1993 and March 31st 2013 at the 4 paediatric centres in Ontario, Canada were identified. Data was abstracted from the time of the index procedure (pyeloplasty) until two years of follow up or until death. All paediatric patients resident in Ontario aged 18 years or younger, who were Ontario residents when the index (initial pyeloplasty) procedure was performed, were included in the study. Patients were excluded if they were not registered in ICES, if sex or date of birth were missing, older than 18 years or were non- residents of Ontario. Further exclusions included death of the patient before the index procedure, those who were not operated on in the one 4 paediatric teaching centres (see paragraph 6.2.1.), if there was no diagnosis of UPJO upon hospital discharge date within 360-days prior to the index procedure (including the procedure date) in DAD or SDS. The cohort was stratified into four, five years block to observe trends over time: 1993-1997, 1998-2002, 2003-2007, 2008-2013.

3.2.4. Outcomes

The primary outcome was reoperation for UPJO. Secondary outcomes were defined as procedures other than reoperation that resulted in either the need for temporary or definitive release of a secondary obstruction; they included bypass/ureterocalicostomy, insertion of DJ stent, delayed stent removal, pyelotomy/dilatation, nephrostomy tube/external drainage and nephrectomy. Length of stay (LOS) and readmission rates were also determined.

3.2.5. Analysis

Data is reported for the complete 20 year period, stratified by year and by centre. The centres are described by the A, B, C or D for the purpose of anonymity. The identification assignment for each institution is not consistent between tables and figures. Privacy regulations do not allow the presentation of any groups with data points <6, these are indicated by NR in tables. Where possible, data were analyzed using standard summary statistics ANOVA for continuous variables, Kruskal-Wallis test and Chi square test (categorical variables). P value <0.05 was considered to represent a significant difference between data sets.

3.3. Results

3.3.1. Patient and Centre Characteristics

A total of 1714 patients from the 4 centres met the criteria for inclusion in the primary cohort (both diagnosis of UPJO and procedures indicating pyeloplasty repair (Table 8).

Inclusion criteria		
Code	Description of code	Frequency
6777	CORRECTION OF URETEROPELVIC JUNCTION	784
1PE80PF	Repair, renal pelvis open posterior [flank] approach Using apposition technique (e.g. suturing)	248
1PE80PFXXE	Repair, renal pelvis open posterior [flank] approach Using local flap	189
1PE80DA	Repair, renal pelvis endoscopic (percutaneous) approach Using apposition technique [e.g. suturing]	171
1PE80LA	Repair, renal pelvis open approach [posterior] Using apposition technique [e.g. suturing]	141
1PE80DAXXE	Repair, renal pelvis endoscopic (percutaneous) approach Using local flap [e.g. Y V, spatulated spiral, vertical, advancing)	124
1PE80LAXXE	Repair, renal pelvis open approach [posterior] Using local flap [e.g. Y V, spatulated spiral, vertical, advancing)	44

Table 8. Distribution of patients undergoing primary pyeloplasty (index procedure) identified by the procedure codes (CCP and CCI)

As expected most primary procedures (>90%) were completed as an inpatient. Of the primary cohort 28.9% of patients were females and 71.1% were males. The mean age of the index surgery was 60.9 months (SD 62.7) and mean 80.7, 71.0, 57.0, 56.9 months respectively in institutions A, B, C and D. There was a significant difference in age of primary operation between institutions (Table 9).

	All		Age of patients undergoing pyeloplasty (index procedure) by institution								p-value (from ANOVA)
	Mean	SD	A		B		C		D		
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Patient age (months)	60.9	62.7	80.7	72.1	71	62.6	57.0	60.7	56.9	61.1	<0.05

Table 9. Age distribution of patients at time of index pyeloplasty shown for the institutions A, B, C and D.

The average number of primary pyeloplasty repairs was 85.7/year for the last 20 years (Fig. 6).

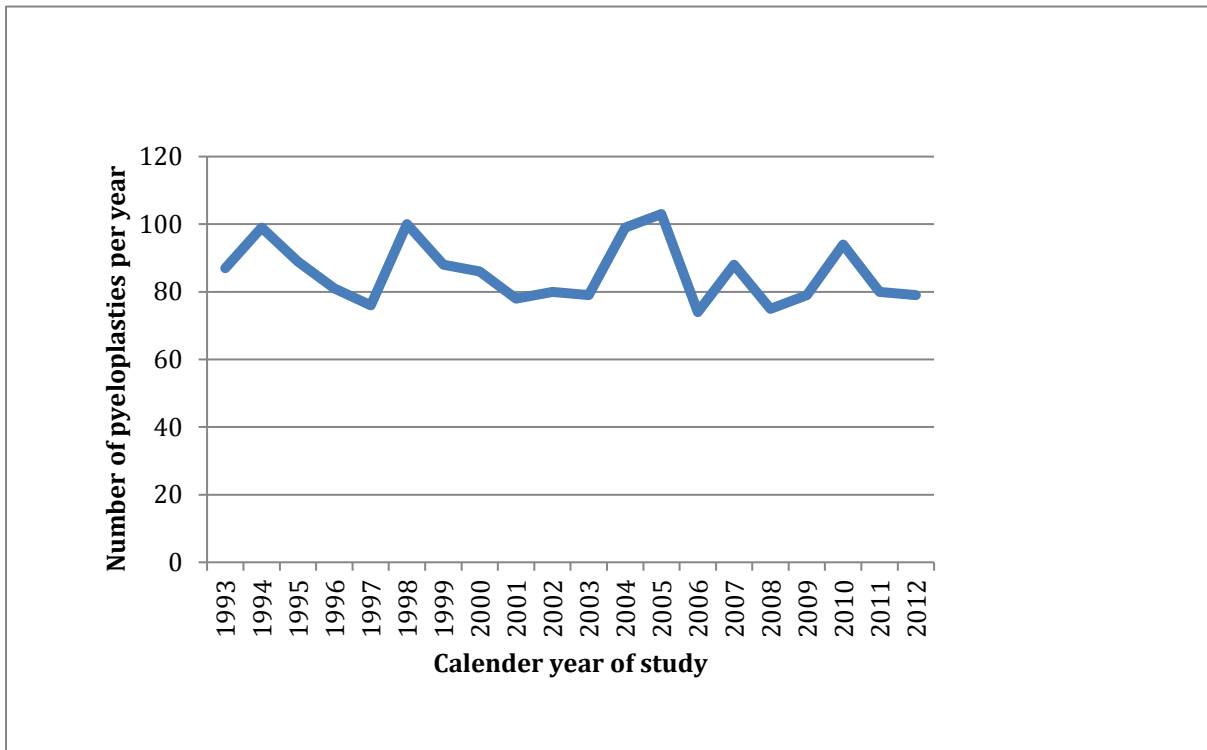


Figure 6. Number of pyeloplasties performed in Ontario over the last 20 years (1993-2013)

The number of pyeloplasties for the eras: 1993-97, 1998-2002, 2003-2007 and 2008-2013 was 432, 432, 443 and 407 respectively. Annual frequency per institution A, B, C and D is presented in Figure 7.

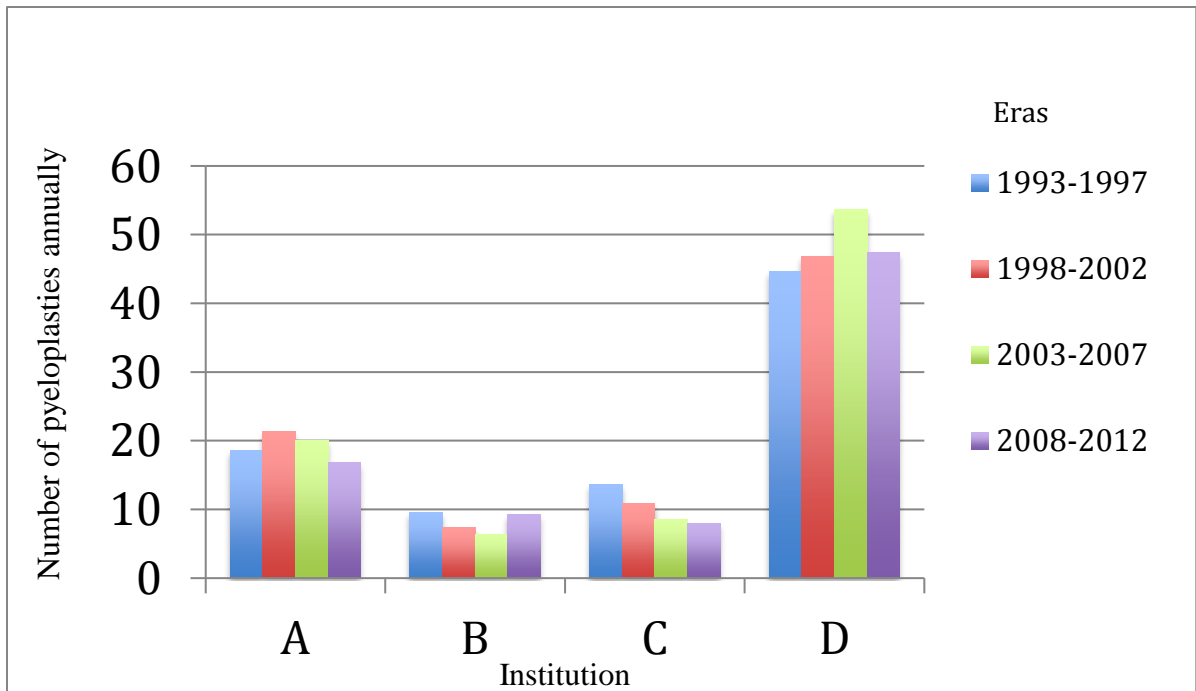


Figure 7. Mean number of pyeloplasties per institutions A, B, C and D, stratified by 4 year time periods. To ensure anonymity of primary and secondary outcomes it is important to note that the identification assignment of the institutions in is this figure is not carried through the remainder of the manuscript.

There is statistically significant difference in patient volume per institution for the 20 years of study (Table 10).

	All		Number of pyeloplasty procedures (Primary exposure) by institution								p-value (from ANOVA)
	Mean	SD	A		B		C		D		
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Patient annual volume	21.43	16.94	19.2	4.42	8.15	3.27	10.25	4.01	48.1	8.66	<0.05

Table 10. Mean annual volume of pyeloplasty (index procedure) procedures per institution. To ensure anonymity of primary and secondary outcomes it is important to note that the identification assignment of the institutions in is this table is not carried through the remainder of the manuscript.

The maximum mean number of primary pyeloplasty repairs per surgeon was 21/year and this has fallen with time to numbers that range from a mean of 4 to 11 cases per surgeon per era (2008-2012: Fig. 8).

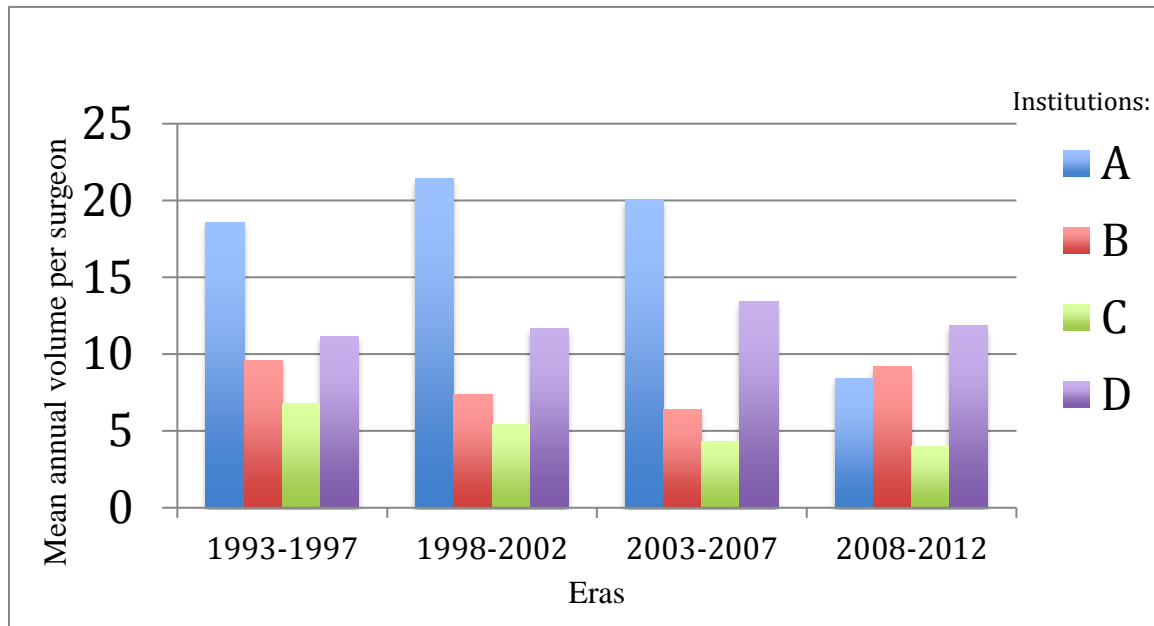


Figure 8. The average number of pyeloplasty repairs per surgeon at institutions A, B, C and D stratified by era. To ensure anonymity of primary and secondary outcomes it is important to note that the identification assignment of the institutions in this figure is not carried through the remainder of the manuscript.

3.4. Outcomes

3.4.1. Primary Outcomes

Following pyeloplasty, 91.1% of patients did not require any other surgical intervention. Four percent (n=68/1714) of the primary cohort went on to require reoperation (primary outcome) and there was no statistical difference in this reoperation rate between institutions (range 3.4-4.9%: $p \geq 0.05$ from Chi-square test: Table 11).

3.4.2. Secondary Outcomes

Secondary outcomes were identified as those surgical interventions other than reoperation. After primary pyeloplasty, 71 patients (4.1%) had an endoscopic procedure either endopyelotomy or dilatation. The number of pyelotomies/dilatations performed at the different institutions ranged from 1.6-5.2% ($p < 0.05$ Chi-square test: Table 11). Fifty four patients (3.2%) required percutaneous drainage or nephrostomy and there was a statistical difference between institutions (range 1.6-7.3%: $p < 0.05$ Chi-square test: Table 11). The number of patients who underwent an ureterocalicostomy is too small to report. Twenty one patients (1.2%) who did not have a stent inserted during the index procedure required a stent insertion within the first 10 weeks after the index procedure. There were 121 patients (7.1%) who had an endoscopy performed more than 10 weeks after the index procedure, which may represent late stent insertion, reinsertion if they were removed, or late stent removal related to prolonged leakage (Table 11). Twelve patients (0.7%) eventually went on to nephrectomy and the numbers are too small to report per institution.

Overall 124 patients (7.2%) were re-admitted to hospital within first 21 days after the operation, and there was a statistical difference between institutions (range 3.7-27.3%: $p < 0.05$: Chi-square test). Overall post-operation LOS was 4.92 days-mean (SD-5.14) and there was statistical difference between institutions (mean range 4.26-7.52%: $p < 0.05$: ANOVA).

Events (secondary outcomes)	All		Outcomes at institutions				p-value (from Chi-square test)
			A	B	C	D	
	Number of events	% of patients, in which the event appeared	%	%	%	%	
Patients who had any surgical intervention after pyeloplasty	153	8.9	11	11.7	6.5	8.9	≥0.05
Reoperation	68	4	4.9	3.4	3.9	4	≥0.05
Pyelotomy/dilatation	71	4.1	4.3	3.9	1.6	5.2	<0.05
Nephrectomy	12	0.7	not reportable				not reportable
External drainage/nephrostomy	54	3.2	3.1	7.3	1.6	2.9	<0.05
Bypass/Ureterocalicostomy	not reportable		not reportable				not reportable
Stent insertion ≤70 days	21	1.2	not reportable				not reportable
Stent insertion/removal >70 days	121	7.1	not reportable				not reportable
Readmission within 21 days	124	7.2	3.7	27.3	3.9	4.9	<0.05

Table 11. Number patients who underwent a surgical intervention following pyeloplasty by institution.

The ability to identify an open versus a laparoscopic pyeloplasty was not possible before 2002. In the period 2003-2007 23.3 percent of all pyeloplasties were performed laparoscopically and this increased to 44.2% during 2008-2012 (Table. 12).

Number (Percentage) of pyeloplasties by era							
	No. of Pyeloplasties since 2002	% of all Pyeloplasties since 2002	1993-1997	1998-2002	2003-2007	2008-2012	p-value from Chi-square test
Open Pyeloplasty	634	37	N/A	N/A	76.7	55.8	<0.05
Laparoscopic Pyeloplasty	296	17.3	N/A	N/A	23.3	44.2	

Table 12. Number (percentage) of pyeloplasties undertaken open or laparoscopically reported by era since 2002.

There was no statistical difference in the number of laparoscopic pyeloplasties between institutions (range 11.2-19.5%: $p < 0.05$: Chi-square test) during the last 20 years (Table. 13). During the time periods 2003-2007 and 2008-2012 when the incidence of laparoscopic pyeloplasties was increasing, the success rate was (91.0 vs. 90.9%) and the reoperation rate (3.8 vs. 4.2%: Table 14).

Number (percent) of laparoscopic pyeloplasties performed in the institutions A, B, C, D for the 20 year study period							
Missing (pre-2002)	All institutions Number	All institutions %	A (%)	B (%)	C (%)	D (%)	p-value from Chi-square test
Open Pyeloplasty	634	37	32.5	34.1	39.6	37.3	>0.05
Laparoscopic Pyeloplasty	296	17.3	17.2	11.2	14.8	19.5	

Table 13. Total number (percent) of laparoscopic pyeloplasties carried out at the individual institutions during the study period.

There was no statistical difference in the reoperation rate between the four eras (range 3.2-4.6%: $p > 0.05$: Chi-square test). Dilatation/ pyelotomy, nephrectomy, stent insertion within 70 days and bypass/ ureterocalicostomy rates were very low and not reportable. There was a statistical difference between eras in the number of nephrostomies that were carried out. Nephrostomy rates decreased with time from 6.5% in 1993-1997 to 1.5% in 2008-2012 (range 1.5-6.5%: $p < 0.05$: Chi-square test). There was a statistically significant decrease in readmission rates between eras from 12% in 1993-1997 compared to 5.2% in 2008-2012 (Table 14).

	All		Outcomes divided by era				p-value (from Chi-square test)
			1993-1997	1998-2002	2003-2007	2008-2012	
	No.	%	%	%	%	%	
Primary Outcome	153	8.9	10.9	6.7	9	9.1	≥ 0.05
Reoperation	68	4	4.6	3.2	3.8	4.2	≥ 0.05
Pyelotomy/dilatation	71	4.1	not reportable				not reportable
Nephrectomy	12	0.7	not reportable				not reportable
External drainage/nephrostomy	54	3.2	6.5	2.3	2.3	1.5	< 0.05
Bypass/Ureterocalicostomy	not reportable		not reportable				not reportable
Stent insertion ≤ 70 days	21	1.2	not reportable				not reportable
Stent insertion/removal > 70 days	121	7.1	not reportable				not reportable
Readmission within 21 days	124	7.2	12	8.1	3.6	5.2	< 0.05

Table 14. Primary and secondary outcomes following pyeloplasty by era (averages (percent) are reported as a combination of all centres).

3.5. Discussion

This study was performed to determine the volume and outcomes associated with pyeloplasty in the paediatric population in Ontario. This study demonstrated that the

overall outcome following pyeloplasty is excellent and has remained stable over the last 20 years. Although there is a statistical difference in the number of pyeloplasties performed between institutions (Table 10), the total number/frequency of these procedures has also remained stable over the study period. The reoperation rate remained at approximately 4% for the 20 years of the study, this is very comparable to previously reported studies [24-30, 51], suggesting that the coding associated with rate of pyeloplasty and redo pyeloplasty is accurate.

Pyeloplasty was chosen as the procedure to investigate the relationship between volume and outcome in paediatric urology, as it is an operation where the principles of the surgery have not changed over the past two decades, the timeframe when this data was collected. The reoperation rate was chosen as the primary outcome rather than mortality because mortality is very rare after this procedure and can also be influenced by other factors besides the post-operative course. The incidence of pyeloplasty remains almost unchanged over the time frame of the study and this also suggests that it is an excellent procedure to study. The number of paediatric urologists performing the procedure has not undergone a significant change since 1993. At the start of the study period there were 8 paediatric urologists in Ontario and at the end of the 2013 there were 9. The data shows that one centre in Ontario provides care to 50% of patients in the province undergoing pyeloplasty, with the remaining 50% of surgeries are split between the 3 other centres. In 2014 Sukuma et al., [48] reported better outcomes following pyeloplasties that were carried out in centres with high volume than the low volume. Hospitals performing 35 open pyeloplasties and/ or and 41 laparoscopic pyeloplasties were considered high volume and hospitals performing 16 open pyeloplasties and/or 13 laparoscopic pyeloplasties were considered low volume. They analyzed 6006 patients and looked at intraoperative and postoperative complications, prolonged length of stay, and excessive hospital charges. As per Sukuma, one of the centres in our study would fulfill the criteria for a high volume centre and the other three would fulfill criteria as low volume centres. However the study by Sukuma did not investigate the volume-outcome relationship per surgeon. In our study, the volume of patients per surgeon has decreased from a mean range of 5-21 patients/ surgeon in the era 1998-2002 to a mean of 4-11 patients/surgeon in 2008-2012 (Fig. 8). Given that the number of redo pyeloplasties is

similar across institutions the data suggests that individual surgeon volume does not affect the primary outcome and those surgeons that perform a mean of 4 or more pyeloplasties per year are experiencing excellent operative success. It is beyond the scope of this study to consider the impact of surgeon experience on the proficiency of the individual surgeon and subsequent patient outcomes but it must be taken into consideration when interpreting results of this nature.

Ninety one percent of patients did not require any surgical intervention following pyeloplasty and 4% required a reoperation. These numbers are very comparable with previous studies. However this is the first study to compare only academic, tertiary paediatric urology centres where patients are only seen by specialty trained urologists with specialized trained staff and paediatric specific resources. Most of the previous studies have combined data from paediatric and adult centres [47, 48]. Due to very low event rates the difference in the number of secondary outcomes per institution is not reportable for nephrectomies, bypass/ureterocalicostomies and for stent insertion within 70 days or stent insertion/removal after 70 days. This in itself reflects the excellent outcomes across the province and within the different institutions. There was significant differences between institutions in the secondary outcome pyelotomy/dilatations, however the number of actual procedures was small (71) relative to the number of patients who underwent a pyeloplasty (1714) and the range of numbers between institutions was also small (1.6–5.2%: Table 11). It is therefore difficult to determine the clinical significance of this finding, but it would certainly suggest that further investigation should be undertaken to determine factors that might identify those patients that would be at risk of stricture following pyeloplasty for UPJ obstruction. There was a significant difference between institutions in numbers of patients undergoing nephrostomy and those requiring readmission within 21 days of the index procedure early in the study period however, nephrostomy and readmission rates then dropped over time (Table 14). This suggests a practice change over time that has migrated towards a common treatment approach between all of the institutions.

It was the original intention of the study to compare volumes and outcomes in patients who underwent pyeloplasty and a stent insertion at the time of the primary procedure with those without stent insertion. However, the code which differentiates

patients who had stent insertion versus those who had no stent inserted at the time of the index procedure is not reliably used. Surgeons may report a stent insertion as a separate procedure at the time of the index operation and on the other hand may consider it part of the index procedure and not record it at all. We found up to 11% of operations reported stent insertion during the index procedure by using a CCI/CCP code that was separate from the operation code (ureteric stent insertion definition 1). We analyzed the incidence of stent removal after the index procedure, without any stent insertion between the index day and removal day (ureteric stent insertion definition 2). This would correspond with stent insertion that was most likely performed during the surgery, but was not coded for at the time of surgery. We found that when the index procedure and both stenting definitions were combined, the percentage of stented pyeloplasties reached 47.8% for all 20 years and 65.8% for pyeloplasties performed between 2008-2012. Sturm et al., 2014 reported a urinary diversion rate of 45% during OP and 83% during laparoscopic procedures [47]. In the one of the biggest Canadian studies in 2008, Braga et al., reported a stent rate of 87% during the pyeloplasty procedure [25]. Although our results are somewhat comparable with the literature stent rates must be interpreted with extreme caution. The need to use a combination of definitions to identify stent insertion at the time of surgery demonstrates that the coding at the time of the index procedure is very inaccurate- if there is a stent removal code but never an insertion code. Furthermore the assumption that a stent removal without a code for a stent insertion is an accurate proxy to calculate the number of stent insertions is also flawed, again it relies on the assumption that insertion did not occur after the index procedure. An additional issue is that stents, which do not require surgical removal or which fall out spontaneously are not captured if the stent insertion is not recorded at the time of the primary procedure. A further limitation of the study is the inability to identify the site of operation (right versus left versus bilateral) using CCI/CCP codes. It is very rare to undertake bilateral pyeloplasty and most authors agree that pyeloplasty should be performed on one side first followed by an operation on the contralateral side 1-2 month later [53-57]. The reoperation rate in our study was reported 6 months after the index procedure and although possible contralateral pyeloplasty be captured as a “reoperation” in that period it is unlikely since most contralateral index events would occur within the 6 month time frame.

This study demonstrated that over 20 years in Ontario the complication rates associated with pyeloplasty are comparable with rates reported by other studies. It also demonstrates that with the exception of dilatation/pyelotomy, nephrostomy and readmission within 21 days, all other outcomes are comparable between centres. Moreover, the incident of nephrostomies and readmission rate are decreasing over time. It is beyond the limits of this study, due to privacy issues, to identify particular centres, nevertheless given differences in dilatation/ pyelotomy between centres further investigation will be required. This may occur in the form of permission to specifically identify centres and then address clinical pathways, surgical technique etc. It may also take the form of a working group with representation from each centre where open discussion and standards of care can be generated.

In summary this study highlights the difficulties of using data abstraction and the quality of the data in the databases themselves. Furthermore it emphasizes the limitations of reporting small numbers of outcomes. These problems are not specific to paediatric urology but are applicable to any surgery that has small index volumes. It certainly raises the need to improve data abstraction, coding and the ability to collect data across Canada in multi centred studies to determine outcomes, especially as it relates to complex paediatric surgical procedures.

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4.0. General Discussion and Conclusions

As outlined in the introductory chapter the outcome of many surgical procedures have been shown to be linked to a number of factors including the clinical condition of the patient, the perioperative care, the complexity of the surgical procedure and the experience of the surgeon. Over the past few decades, many studies, across a variety of surgical procedures have shown that the outcomes of certain surgical procedures are related to the volume of operations performed at that center. Patients treated in hospitals performing more operations are more likely to have fewer complications [1,2].

Pediatric surgery volume outcome studies are difficult to undertake because we have a limited number of patients and certain procedures are rarely performed. Comparing the outcomes between centers is thus difficult, but comparing single surgeon experience in particular centers may be even more challenging. We compared patient related outcomes at the 4 academic paediatric centres in Ontario, which are similar in structure, staff availability, resources and organization. It was anticipated that a province with such a large population would provide volumes of surgical procedures that would allow us to study a volume/outcome relationship.

We planned to compare 2 complex paediatric surgical procedures, which are only performed in paediatric tertiary centers by specialized paediatric surgeons. The technique of the procedures chosen for the study was well known and relatively common, was treated the same way in different centers and has not changed throughout the time. We have chosen procedures, on which comorbidities have minimal impact on outcomes, however it is acknowledged that it is impossible to choose procedures of which treatment outcome is completely independent from other comorbidities. Pyeloplasty is an example of operation, which comorbidities, if even exist, are likely not related to the outcome of the procedure. Although patients with TEF may have comorbidities and sometimes they can be quite serious, like cardiac defects, the actual complications of TEF repair are likely related to other congenital problems.

The purpose of this study was to determine the volume of two complex pediatric surgical procedures at tertiary centers in Ontario over the last 20 years. We studied the outcomes and explored the possible relationship between outcomes and volume. The study incorporated the use of ICES data sets to determine the volume and outcomes of the complex surgical procedures tracheoesophageal fistula (TEF) repair and pyeloplasty.

In brief a population based retrospective cohort study of all pediatric patients undergoing TEF repair and pyeloplasty at tertiary pediatric centers in Ontario was carried out. In Ontario each patient encounter is recorded in large population-based health care data bases dating back to 1988. These datasets were linked using unique, encoded identifies and analyzed at the ICES. Specific codes for congenital disease like TEF and UPJO were chosen from ICD-9 and ICD-10 codes and the cohort of patients with those defects were assigned. Repair procedures codes for those congenital diseases were chosen from CCI and CCP codes lists. The index procedure of pyeloplasty and TEF repair were identified as described in detail in chapters 2 and 3. The primary outcome was identified and was the same for both procedures – reoperation, which was similar to the index procedure. As reoperations, we also included procedures, which are equivalent to reoperation like gastric pull up-equivalent of re-do TEF repair or calicoureterostomy-equivalent of re-do pyeloplasty. Secondary outcomes were chosen based on clinical experience and review of the literature and were reflection of possible clinical pathway after these kinds of operations. They were different for different operations and take into account the complexity of the procedures. Secondary outcomes of TEF repair were: other surgical intervention on bronchus, trachea and esophagus and procedures related to esophageal obstruction like: insertion of a gastrostomy tube, dilatations of esophageal stricture or radiological contrast study related to dysmotility. Secondary outcomes of pyeloplasty, although different than in TEF, are the same in nature: related to obstruction in UOJ segment: dilatations, catheterization drainage or nephrostomy.

The data was presented for all institutions and for individual centers but the centres were de- identified as A,B,C or D. The labelling of centres was also not consistent to prevent

association of results with outcomes of specific centres. The cohorts were stratified into four five years block to observe trends over time: 1993-1997, 1998-2002, 2003-2007, 2008-2012. We analyzed the data in these block periods in an attempt to maximise the number of patients per data point. All the patients with diagnosis codes and repair codes were included into the main cohort.

Four hundred and sixty five patients met the criteria for inclusion in the primary cohort of TEF repair. This is a very small number to look at volume outcome relationships if the volume is then broken down further into numbers per institution and era and the occurrence rate of the outcome is low. Reporting of outcomes then becomes limited by the privacy regulations that prevent the presentation of groups that contain less than 6 data points in any of the reporting cells within that specific analysis. In contrast, 1714 patients met the criteria for inclusion in the primary cohort of patients having undergone pyeloplasty. This cohort is four times bigger than the TEF cohort and the numbers are comparable to that of another recently published Canadian study [3]. The average number of primary TEF repairs was 23.25/year for the last 20 years and although one institution carried out one third of the TEF repairs with the remainder being split between the other 3 centers, the actual volume per surgeon was very similar. Similarly the average number of primary pyeloplasties was 85.7/year for the last 20 years with one of the institution performing approximately 50% of the case. Although data is reported by individual surgeon it may not reflect the expertise around the operating table at the time of procedure. For example in some of the smaller centers 2 surgeons will often attend index cases. Also in resident training programs a chief resident may have had exposure to anywhere between 4-15 TEF repairs per year and the same period the attending surgeon may have only undertaken 1 repair. Such information cannot be obtained from the data bases used in this study and would require review of the operative record from each individual chart.

Both TEF repair and pyeloplasty reoperation rates (5.3% and 4% respectively) are low and similar to that reported in the literature [3, 4]. There was no statistical difference

between institutions in the rate of reoperation following index pyeloplasty and unfortunately due to the limitations as described above such as low volumes, primary outcome event rates and the limitation of reported only cell numbers greater than 6 statistic could not be presented for TEF. These findings highlight that in order to determine if a volume outcome relationship exists for recurrent TEF the paediatric surgical community to across Canada would have to combine data and potentially stratify outcomes into low versus high outcome centres. This low vs. high volume centers comparison would be especially beneficial when we would recruit more centers from other provinces and we would be able to compare at least few high volume centers and several lower volume institutions.

However this data does suggest that that the rate of recurrent fistula and the need for reoperation in Canada is low. The Canadian pediatric surgical community is very small and this in its self provides a number of checks and balances. Most of the pediatric surgeons currently working in Ontario were trained in the province or in Canada. It is likely that a centre with very high complication rates would quickly be identified.

Secondary outcomes following TEF repair reflect not only the outcome of the surgery, but also reflect clinical care pathways and are likely more heavily influenced by patient comorbidities. For example the rate of gastrostomy tube insertion was significantly different between institutions (range 15.2 -37.7%). Children with TEF have often problems with poor esophageal motility and dysphagia, resulting in poor nutritional status of the patient. Some surgeons prefer conservative treatment and nutritional supplementation via a nasogastric tube while others proceed promptly to gastrostomy tube insertion. It certainly would be interesting to look more closely at those centres with a higher gastrostomy insertion rate and determine patient co-morbidities, the reason for gastrostomy tube insertion and who for example was making the decision for gastrostomy tube insertion, a gastroenterologist, complex feeding team or a surgeon. Otherwise, we would like to underline that gastrostomy is not a pure complication. It is reassuring that the rate of postoperative esophageal dilatation following TEF repair was similar between institutions, since this likely reflects the success of the surgical technique. An esophageal stricture is very common in patients following TEF repair with reported rates varying

from 4 to 80% in the literature [4, 5], very similar to those found in our study. There was a statistical difference between institutions in the category of other oesophageal repair (range 17.5-23.9%). It is difficult to interpret this data, it is likely that number of stricture repairs is overestimated as there was no CCP code that described an esophageal dilatation, just esophageal stricture repair. It is likely that during the first 10 years of the study the code for stricture repair was used to describe an esophageal dilatation. Furthermore, this group of procedures includes over 85 codes. Most of them are related to repair of the esophagus likely following dilatation of a stricture, as described above or they were used to describe treatment of a leak or resection of the esophagus for a recalcitrant stricture. It may also be related to a different approach to esophageal strictures such as a preference for limited esophageal resection rather than dilatation. This certainly raises the need to look more closely at this outcome either at an institutional level or more regionally at the approach to esophageal stricture. This also highlights the fact that accurate data relies upon the accurate coding of the procedure. Many of codes are not precise or unambiguous and as we presented, there is only one code representing TEF repair or Pyeloplasty. Also the codes need additional interpretation as they may be used in similar, but not the same procedures and it reflects the code construction: very wide definitions of procedures (from older CCP codes list) and detail oriented, but also not only one code, which represent actually the same operation (recent, CCI codes).

Secondary outcomes following pyeloplasty were variable between institutions. For example there was a significant difference in the number of pyelotomy/dilatations and percutaneous drainage procedures following pyeloplasty. However in reality the number of these interventions is small and consequently it is difficult to determine the clinical significance in terms of assessing the success of the initial pyeloplasty. The difference in the rate of nephrostomy tube insertion and readmission rate following the index procedure suggests a practice change over time as both have decreased in the last eras of the study. The incidence of stent insertion after the index procedure is significantly different between institutions; this may be related to surgeon preference for stent

insertion at the time of index procedure. If the surgeon did not originally place a stent and a leak occurs they then have to place a stent- a situation that could be avoided if the stent was placed at the original operation. Although many paediatric urologists place a stent during the index procedure, they do not code it separately. Thus is it difficult to determine accurately what proportion of patients a stent had inserted at the index procedure. This is an example of the many issues that are encountered when using data which relies on accurate coding by the data abstracters, the availability of appropriate codes to assign to the procedure and the accuracy of the operative/nursing notes, discharge summaries from which the data abstracter obtains the appropriate codes. This limitation has to be considered for all data in this study.

In conclusion we have demonstrated that, although the data for our study was collected from the entire province over the last 20 years, it is still a small paediatric cohort. Our study showed that the recurrence rate of TEF and UPJO in Ontario is very small, which demonstrates overall very good outcomes. The volume of patients was so small that we were unable to demonstrate volume and outcome relationships. This study highlights the difficulties of data abstraction and the quality of the data in the databases themselves. It emphasizes the limitations of reporting outcomes from small numbers associated with the paediatric environment. The differences in secondary outcomes will require further investigation, which may occur in the form of permission to specifically identify centers and then address clinical pathways, surgical technique etc. This study also raises the need to improve data abstraction, coding and the ability to collect data across Canada in multi-centered studies to determine outcomes, especially as it relates to complex paediatric surgical procedures.

4.1. References

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5.0. Appendices

Appendix A.

Example of the inclusion criteria used in the cohort build. (Tracheoesophageal Fistula (TEF), Pyeloplasty, Ventriculo-peritoneal shunt (V-P shunt))

TEF repair	Pyeloplasty	V-P shunt insertion
Patients who have unique ICES identifiers in the database. We included patients in fiscal years 1993 to 2013 (fiscal year runs from April 1st to March 31 st of the following year).		
Patients who were Ontario residents at the time of index procedure.		
Patients who had index procedure performed at a paediatric teaching centre in Ontario including following cities: London, Ottawa, Hamilton, or Toronto.		
Age<180 days	Age<18 years	Age<18 years
ICD-9 and ICD-10 codes for TEF diagnosis	ICD-9 and ICD-10 codes for congenital UPJ obstruction	ICD-9 and ICD-10 codes for hydrocephalus
CCP and CCI coded for TEF repair	CCP and CCI coded for Pyeloplasty	CCP and CCI coded for V-P shunt insertion

Appendix B.

Example of the exclusion criteria used in the cohort build
(Tracheoesophageal Fistula (TEF): Pyeloplasty, Ventriculo-peritoneal shunt (V-P shunt))

TEF repair	Pyeloplasty	V-P shunt insertion
Patients not registered in ICES		
Patients who were not Ontario residents at the time of index procedure.		
Patients who had index procedure performed at a different centre than Ontario (including following cities: London, Ottawa, Hamilton, or Toronto)		
Age>180 days	Age>18 years	Age>18 years
ICD-9 and ICD-10 codes different than for TEF diagnosis (exclusion list)	ICD-9 and ICD-10 codes different than for congenital UPJ obstruction	ICD-9 and ICD-10 codes different than for hydrocephalus
CCP and CCI coded for different than TEF repair	CCP and CCI coded different than for Pyeloplasty	CCP and CCI coded different than for V-P shunt insertion
Patients who died prior to the index procedure		

Appendix C.

Example of procedure (CCP and CCI) and diagnosis codes (ICD 9 and 10) that were used to identify the primary cohort. These represent codes that were used to create the primary cohort for tracheoesophageal fistula repair (Chapter 2.).

Procedure code	Procedure description
1NA84QE	Construction or reconstruction, esophagus with tracheoesophageal fistula repair Open thoracic approach
1NA84QJ	Construction or reconstruction, esophagus with tracheoesophageal fistula repair Open thoraco-abdominal approach
1GJ86ME	Closure of fistula, trachea open approach for fistula terminating at esophagus [e.g. tracheoesophageal fistula] with simple apposition for closure [e.g. suture]
1GJ86MEW3	Closure of fistula, trachea open approach for fistula terminating at esophagus [e.g. tracheoesophageal] with simple apposition and fibrin [glue]
1GJ86MEXXA	Closure of fistula, trachea open approach for fistula terminating at esophagus [e.g. tracheoesophageal fistula] using autograft
1GJ86MEXXE	Closure of fistula, trachea open approach for fistula terminating at esophagus [e.g. tracheoesophageal fistula] using local flap [e.g. strap muscle]
Diagnosis Code	Diagnosis description
4363	Closure of other fistula of trachea
5441	Esophagoesophagostomy (intrathoracic)

Appendix D.

Example of Cohort build; TEF repair (Chapter 2)

Build cohort step	No of excluded	No of included
Original cohort	Before Exclusion	825
Missing sex or age	9	816
Death prior to index date	0	816
Age \geq 180 days	322	494
Non-Ontario resident	NR (included in step below)	suppressed
No diagnosis of CEF 60 days prior to index date	NR (included in step below)	suppressed
Procedure not performed at paediatric teaching	NR (included in step below)	suppressed
Evidence of other esophageal injury	29	465

6.0. **Damian Dylkowski-Curriculum Vitae**

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