A Decade of Pediatric Tracheostomies: Indications, Outcomes, and Long Term Prognosis.

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Abstract

Objective: To define the mortality and long-term outcomes of children undergoing tracheostomy.

Design: Retrospective chart and Texas Department of Health Bureau of Vital Statistics review of patients admitted to a Pediatric Intensive Care Unit who underwent a tracheostomy between 2001 and 2011. Mortality and decannulation rates were compared based on tracheostomy indication and age.

Subjects: 426 patients admitted to a Pediatric Intensive Care Unit in a large tertiary children's hospital.

Results: The median patient age was 1.5 years (3 days - 24 years). Primary indications for tracheostomy included: a) airway obstruction, b) congenital neurologic disease, c) acquired neurologic disease, d) congenital respiratory disease, and e) acquired respiratory disease. Overall, 98 patients (23%) died during the study period, and 75th percentile survival time was 5.9 years (95% CI: 3 - 8). Patients undergoing a tracheostomy for airway obstruction were the least likely to die; while patients with acquired neurologic disease were most likely to die. A total of 163 patients (38%) were decannulated, and 50% were decannulated at 1.2 years (95% CI: 0.9 - 1.5). Patients with congenital neurologic disease were the least likely to undergo decannulation. Over half of the patients were discharged from the hospital requiring some form of mechanical respiratory support in addition to their tracheostomy.

Conclusions: In this largest cohort of long term follow-up to date, we have shown the overall risk of mortality varied according to the indication for the tracheostomy. We were unable to

determine exact causes of death. The likelihood of being decannulated also correlates with the underlying indication for the tracheostomy.

Introduction

Over the past several decades, advances in medicine and technology have led to increased survival of patients admitted to Pediatric Intensive Care Units (PICUs) ¹. However, this increased survival is often accompanied by new or worsening co-morbidities that result in intermediate or long-term dependence upon technology. One group of technology-dependent survivors is the estimated 4800+ infants and children who undergo a tracheostomy each year in the United States, with hospital charges alone totaling almost \$1 billion ². The spectrum of indications for placement of a tracheostomy in children is broad, and range from provision of an airway to overcome obstruction to long term need for a ventilator ^{3,4}. The underlying conditions leading to the need for a definitive airway include neurological and neuromuscular disease, lung disease, and heart disease. In the current era, there are a proportion of patients who undergo tracheostomy without a clear prognosis, while others have a disease with an unpromising future. Tracheostomies may also be used as a short-term or long-term rehabilitation tool in patients with a promising prognosis. Many of these children also require long-term ventilation⁵. The heterogeneity and complexity of the pediatric tracheostomy population makes them challenging to study.

The decision to proceed with a tracheostomy is a difficult one for families. Healthcare providers can reliably counsel families about the immediate surgical risks and potential early benefits of a tracheostomy. They can also train and educate families in the care of a child with a tracheostomy and can assist with providing the required medical supervision for the care of the

child at home. However, while there are reports of longer term outcomes in infants with a tracheostomy who have been discharged from the neonatal intensive care unit (NICU), the data from the PICU population is less robust⁶⁻⁹. Thus, the ability of healthcare workers to advise the family on the long-term impact of a tracheostomy is very limited. The purpose of this study is to review our extensive experience in children discharged from the PICU with a new tracheostomy with a focus on long-term outcomes including survival, disease burden, and duration of the need for tracheostomy.

Methods

This study was approved by the Institutional Review Boards at Baylor College of Medicine and the Texas Department of Health Bureau of Vital Statistics. Patients who had a tracheostomy placed between August 2001 and August 2011 were identified by review of an internal Tracheostomy Performance Improvement Database, originally designed to record caregiver tracheostomy training in the Progressive Care Unit (PCU) at Texas Children's Hospital. The 36 bed PCU is an intermediate care unit that is staffed by critical care physicians, advanced providers, and specialized nursing staff and provides care for technology-dependent patients and training for caregivers in order to transition patients out of hospital. All tracheostomies were performed by pediatric otolaryngologists as an open procedure in the operating room under general anesthesia. Patients underwent a 5-7 day period of sedation in the immediate post-operative period in the PICU or cardiac ICU to promote stoma healing. After stoma healing and stabilization of underlying disease, patients were then transferred to the PCU. Additional criteria for transition to the PCU included discontinuation of vasoactive drugs and weaning (or discontinuation) of sedating agents. Additional ventilator weaning and transition to a

home ventilator (if necessary) was performed in the PCU. In the PCU, families received training on tracheostomy cannula exchange, basic cardiopulmonary resuscitation (CPR), tracheostomy CPR, bag-mask ventilation, suctioning and other skills needed to care for a child with a tracheostomy as outlined by the American Thoracic Society.¹⁰

After discharge, the majority of patients are followed in a Special Needs Clinic that serves as a medical home and coordinates care with pulmonary and otolaryngology and other specialists as needed. Follow-up care, home equipment needs, family support, and weaning closely follow the recent American Thoracic Society Clinical Practice Guideline for pediatric patients with home invasive ventilation.¹¹ In general, home nursing and additional support were determined by the level of need of the patient, but ultimately dictated by allocated resources (generally according to payors) and additionally at the discretion of the primary caregiver(s).

Included in this review are all infants, children, adolescents and young adults with a new tracheostomy whose family or caregiver completed the tracheostomy care training program in the PCU. Neonates who received their tracheostomy and were cared for in the Neonatal ICU were excluded, as were children who transferred to another facility post-operatively without receiving tracheostomy care training in the PCU. Patients were followed until August 2012 or death – whichever occurred first. We anticipated it would take up to one year after the end of data collection to locate and investigate death records.

Clinical Data

Peri-operative details recorded included indications for tracheostomy, diagnoses, co-morbidities at the time of discharge, date of tracheostomy, hospital admission and discharge dates, ventilation and oxygen requirements at discharge (where appropriate), number of

medications at discharge and doses per day (as a surrogate indicator of burden of care at home), as well as other technological dependencies, e.g. gastrostomy tube or long-term central line. All enteral, parental, and inhaled/respiratory medications were included. Primary indication for the tracheostomy was categorized as:

1. acquired respiratory
2. congenital respiratory
3. acquired neurological
4. chronic neurological
5. anatomic airway obstruction

Indications considered to be primarily anatomical airway obstruction (congenital laryngeal stenosis, Pierre Robin syndrome, acquired subglottic stenosis) were categorized separately. This categorization was performed by three clinicians who participate in the tracheostomy training program. See Appendix 1 for examples of diagnoses in each category. Ventilation requirements were categorized based on the premise of burden (fulltime, partial or none) and cost (ventilator, CPAP and None).

Mortality Data

Death dates were determined by reviewing hospital medical records, the internal tracheostomy database, and the Texas Department of Health Services Bureau of Vital Statistics using probability matching software (Registry PlusTM Link Plus)¹² for the entire cohort.

Analysis

Patient demographics and clinical characteristics were summarized by frequencies with percentages or medians with minimum and maximum values. Summary statistics for time-to-events were summarized by the 50th (i.e., median) or 75th percentiles with 95% confidence intervals. Time to decannulation and death were independently estimated using Kaplan-Meier curves and Cox proportional hazards modeling. Observations were considered censored for decannulation on the last date of contact if the patient was lost to follow-up or died prior to decannulation. Observations were censored for mortality on the last date of contact if the patient was lost to follow-up and no date of death could be identified through any method described above. The log-rank test statistic was used to compare survival curves between groups. Overall statistical significance was assessed at the 0.05 level. If significant, then all pairwise comparisons were assessed using a Bonferroni correction for multiple comparisons. The Cox model was used to estimate unadjusted and adjusted hazards ratios for decannulation and mortality. The proportional hazards assumption was tested using a time-dependent covariate, and a change point for the relative risk was determined by maximizing the log partial likelihood. Statistical significance was assessed at the 0.05 level, and SAS software (SAS Institute Inc. 2011. Base SAS® 9.3 Procedures Guide. Cary, NC: SAS Institute Inc) was used for all analysis.

Results

Our database search revealed 428 children who underwent a new tracheostomy and whose caregivers completed tracheostomy training between 2001 and 2011. Two patients were subsequently excluded from the analysis because the date of their tracheostomy could not be determined. The final study cohort consisted of 426 children. The general demographics of our cohort are summarized in Table 1. The median patient age at tracheostomy was 1.5 years, and age ranged from 3 days to 24 years. Patients were predominantly male (58%) and greater than 1

year of age at the time of tracheostomy (59%). The most common indication for the tracheostomy was a congenital neurological disease (33%).

Table 2 summarizes clinical characteristics for patients in this study. The median hospital length of stay (LOS) for the admission involving the tracheostomy was 50 days (95% CI 45, 54). The median LOS prior to tracheostomy was 17 days (95% CI: 15, 21) with a median post-operative LOS of 31 days (95% CI: 28, 33). Slightly over half of the patients had some degree of ventilator dependency at the time of hospital discharge. We found patients were sent home on a median of 5 medications and 12 doses a day.

Overall, 98 (23%) patients died during the study period. However, the exact date of death for one patient was not known. This patient was censored at the last known date that the patient was alive for survival analysis purposes (e.g., Kaplan-Meier curves and Cox proportional hazards modeling). Figure 1 presents the Kaplan Meier curve for overall time-to-death. The 75th survival percentile was 5.9 years (95% CI: 3.0, 8.0) from the time of tracheostomy placement. Log-rank tests for univariable analysis of Kaplan Meier curves showed that indication for tracheostomy ($P=0.02$) and a diagnosis of cancer ($P=0.01$) were both significantly associated with mortality. Among all pairwise comparisons for tracheostomy indications, patients with acquired neurologic indications were more likely to die compared with patients who had airway obstruction (Bonferroni adj $P=0.03$, Figure 2). Although not significant at the 0.05 level, patients with chronic respiratory disease also tended to be more likely to die compared with airway obstruction indications (Bonferroni adj $P=0.08$). No other pairwise comparisons were significantly different between indications (Bonferroni adj $P\geq 0.38$). Neither patient gender ($P=0.38$) nor age ($P=0.61$) were significantly associated with mortality. After simultaneously adjusting for all variables in a Cox Proportional Hazard model, only cancer ($P=0.02$) and

indication for tracheostomy ($P=0.04$) maintained statistically significant associations with mortality. The risk of death among cancer patients was about 2.1 times (95% CI: 1.1, 4.1) greater than patients who did not have cancer. Patients with acquired neurological (HR=2.3, 95% CI: 1.1, 4.8), congenital neurological (HR=2.2, 95% CI: 1.1, 4.2), and congenital respiratory (HR=2.5, 95% CI: 1.2, 5.2) indications were significantly more likely to die than airway obstruction indication patients. Patients with acquired respiratory indications did not show a statistically significant increased risk of death (HR=1.2, 95% CI: 0.4, 2.9). (Figure 2).

Overall, 163 (38%) patients underwent decannulation (Table 3). Figure 3 presents the Kaplan Meier curve for probability of decannulation with the 75th percentile being 1.2 years (95% CI: 0.9, 1.5) and the median time being 5.3 years (95% CI: 3.2 - ∞). Log-rank tests for univariable analysis of Kaplan Meier curves indicated that age group at tracheostomy ($P=0.04$), indication for tracheostomy ($P<0.0001$), and cancer ($P=0.04$) were significantly associated with decannulation time. Neither patient gender ($P=0.66$) nor heart disease ($P=0.85$) were significantly associated with decannulation time. Among all indications for tracheostomy, congenital neurologic patients were significantly less likely to be decannulated compared with any other indication (Bonferroni adj $P<0.0001$) (Figure 4). Other pairwise comparisons between indications showed no differences (Bonferroni adj $P\geq 0.06$).

Analysis of time-varying covariates suggested the hazards for decannulation were not proportional for age group, indication, and heart disease ($P=0.005$). That is, the risk for decannulation associated with each of these factors significantly depends on the time since tracheostomy. The risk of decannulation changed at about 1 year after surgery, and subsequent analysis was stratified at the 1 year mark. Table 4 summarizes unadjusted and adjusted Cox model results. Investigation of predictors for decannulation showed that gender and cancer were

not significantly associated with decannulation after adjusting for age, tracheostomy indication and heart disease. Children older than 5 years at the time of their tracheostomy were more likely to be decannulated during the first year compared with younger patients. However, among patients who have had the tracheostomy for at least one year, older patients (>5 at the time of tracheostomy) were significantly less likely to have a decannulation compared with younger patients. Patients undergoing a tracheostomy for airway obstruction, acquired neurologic disease, and congenital or acquired respiratory disease were all more likely to be decannulated compared with congenital neurologic patients before and after the 1-year time point. Heart disease patients were less likely to be decannulated within the first year compared with patients without heart disease; however, there was no difference between groups after the 1 year mark.

Discussion

This review represents the outcomes for one of the largest, most comprehensive cohort of pediatric ICU patients discharged home with a tracheostomy. We have shown that there is significant mortality (23%) in this population over time. We also found that 53% of children needed some type of ongoing ventilation support at the time of hospital discharge and over two thirds of the patients also had a gastrostomy. The median time with a tracheostomy was five years. Predictors of mortality were the presence of acquired neurological disease or a diagnosis of cancer. Half of survivors were decannulated at latest follow-up, and older age at time of tracheostomy and the presence of neurological disease were associated with inability to decannulate.

The majority of published studies of pediatric tracheostomy are from small cohorts, frequently confined to a specific population (e.g. cardiac patients or those in a home ventilator

program)¹³⁻¹⁷. One large recent cohort study of over 1600 pediatric tracheostomies was limited to hospital outcomes, with an in-hospital mortality rate of 5.6%. This large United Kingdom study did not track patients after discharge and did not address decannulation rates¹⁸. A second large database study showed an in-hospital mortality of 6.6%¹⁶. A recent study of 885 neonatal ICU babies with tracheostomies demonstrated an in-hospital mortality of 14%, but did not track outcomes after hospital discharge.²⁸ In comparison, our in-hospital mortality involved 8 patients (1.9%) A handful of larger and more heterogeneous cohorts reveal variable outcomes, with mortality rates of between 9% and 39%^{18, 21-8}. Even more variable were the reported tracheostomy decannulation rates ranging from 12% - 75%. No two studies categorized indications for tracheostomy in the same way, which may explain some of the variation in mortality and decannulation rates between these studies.

Our study shows important differences in prognosis depending on underlying indication for tracheostomy. This can provide clinicians with some very useful data when counselling families and caregivers regarding what to expect for their individual child. It also highlights the potential value of utilizing a common categorization scheme and definitions that could allow for outcome comparisons between institutions. For instance, in our study, the airway obstruction group consisted mainly of congenital craniofacial anatomic issues and while others have used that category for patients undergoing an emergent tracheostomy for infectious epiglottitis or croup^{26,29}. The latter groups would be expected to decannulate quickly and have a much lower mortality rate, but are very rare in our setting.

Outcomes appear to be significantly worse for patients who receive a tracheostomy for neurologic indications, especially those with congenital neurologic diseases. Patients who undergo a tracheostomy for respiratory issues, either acquired or congenital, have a better

prognosis in terms of likelihood of decannulation. This information may be helpful for clinicians and families in determining which patients might benefit from a tracheostomy.

Understanding the likelihood of decannulation may also assist with decision making. The finding that older children were more likely to be decannulated during the first year after tracheostomy placement may reflect the use of tracheostomy as a rehabilitation tool. These results are not as encouraging for families of children with congenital neurological issues in regards to decannulation. Those patients were least likely to undergo decannulation.

Limitations of study

This study is limited by the retrospective nature of the review. We anticipate a few patients may have moved out of state or returned to their country of origin resulting in our inability to capture their mortality or decannulation date, although we do not suspect this number was high enough to substantially change the results. These outcomes reflect the process of patient selection, education, and long-term management at a single medical center in the southwestern United States. These mortality and decannulation rates may not be reflective of the outcomes of other tracheostomy programs, especially those without formal discharge educational programs or those who discharge patients to long-term care facilities, which is an option in some geographic areas. A significant limitation relates to the lack of causes of death which would undoubtedly strengthen the analysis and overall message for clinicians and families. After reviewing several death certificates, we found great variability among coroners and medical examiners in documentation of the primary acute cause of death verses underlying chronic diagnosis as cause of death. After finding several discrepancies, we determined we could not obtain accurate data and any attempt to report it would be misleading as to the actual causes of

death. This is clearly an area which warrants further study and would best be done in a prospective fashion.

Conclusion

Children undergo a tracheostomy for a variety of indications and diagnoses. Significant prognostic differences in mortality and decannulation rates exist based on these indications. Of the original cohort, one-quarter of the patients were decannulated within 1.2 years, and one-quarter died within 5.9 years. One third of all patients were decannulated within our 10 year study period. The majority of children who undergo a tracheostomy for neurologic indications, either congenital or acquired, are not likely to be decannulated. A standard categorization scheme for tracheostomy indication is needed to allow for comparisons between centers and countries.

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Figure Legends

Figure 1. Overall survival probability of the entire cohort of patients over time

Figure 2. Survival probability among different groups of patients based on the indication for the tracheostomy. Airway obstruction (AO), Neurologic acquired (NA), Neurologic congenital (NC), Respiratory acquired (RA), Respiratory congenital (RC).

Figure 3. Probability of decannulation over time for the entire cohort

Figure 4. Decannulation probability among different groups of patients based on the indication for the tracheostomy. Airway obstruction (AO), Neurologic acquired (NA), Neurologic congenital (NC), Respiratory acquired (RA), Respiratory congenital (RC).

Appendix 1 Categorization Scheme of Tracheostomy Indications and Diagnoses

Airway Obstruction (AO) (99 patients)

Pierre Robin Sequence
Subglottic stenosis
Laryngeal papillomatosis
Nasopharyngeal lymphoma
Goldenhar syndrome
Dwarfism with small glottis
Treacher Collins syndrome
Subglottic hemangioma
Tongue sarcoma
Laryngomalacia
Bilateral vocal cord paralysis

Acquired Respiratory Disease (RA) (40 patients)

Idiopathic pulmonary hemorrhage
ARDS resulting in chronic lung disease
Stevens Johnson syndrome with bronchiolitis obliterans
Prolonged mechanical ventilation
Ventilator induced lung injury
Scoliosis causing restrictive lung disease

Congenital Respiratory Disease (RC) (99 patients)

Chronic lung disease from Bronchopulmonary dysplasia
Pulmonary hypoplasia
Pulmonary hypertension
Achondroplasia with restrictive lung disease
Surfactant deficiency
Cystic fibrosis

Acquired Neurologic Disease (NA) (82 patients)

Hypoxic ischemic injury from submersion or cardiac arrest
Brain tumor
Traumatic brain injury
Non-accidental head trauma
Stroke
Encephalitis
Viral meningitis
Transverse myelitis
Arterio-venous malformation
Para-spinal ganglioneuroma

Congenital Neurologic Disease (NC) (139 patients)

Duchenne's muscular dystrophy

Spinocerebellar ataxia

Spinal muscular atrophy

	N = 426
Age	176 (41%)
< 1 year	102 (24%)
1-5 years	148 (35%)
>5 years	
Sex	248 (58%)
Male	178 (42%)
Female	
Primary Indication for Tracheostomy	66 (16%)
Respiratory – congenital (RC)	40 (9%)
Respiratory – acquired (RA)	139 (33%)
Neurological – congenital (NC)	82 (19%)
Neurological – acquired (NA)	99 (23%)
Anatomical obstruction (AO)	
Associated Diagnoses	32 (30%)
<i>Heart disease (106)</i>	17 (16%)
Respiratory - congenital	21 (20%)
Respiratory – acquired	7 (6%)
Neurological – congenital	29 (27%)
Neurological – acquired	1 (2.6%)
Anatomical obstruction	5 (13%)
<i>Oncologic process (38)</i>	2 (5%)
Respiratory – congenital	23 (60%)
Respiratory – acquired	7 (18%)
Neurological – congenital	
Neurological – acquired	
Anatomical obstruction	

Central hypoventilation
Zellweger Syndrome

Table 1. Characteristics of
Pediatric Tracheostomy Cohort

**Table 2. Peri-Operative
Hospital Course**

	Patients	Summary Statistic
Median Hospital LOS	424*	50 days (95% CI: 45, 54)
Oxygen requirement at discharge (%pts)	181/405	45%
Ventilator dependent at discharge	194/411	47%
None	143/411	35%
Full Time	74/411	18%
Part Time		
Medications at Discharge**	397	5 (0, 36)
Median number per patient (range)	397	12 (0, 55)
Median daily doses per patient (range)		
Technology Dependency at Discharge	292/426	69%
Gastrostomy tube	35/426	8%
Central venous line	32/426	8%
Ventriculo-peritoneal shunt	3/426	1%
Vagal nerve stimulator		

*Date of admission was unknown for 2 patients and they were excluded for LOS data. 8 patients died prior to discharge and were considered censored observations for this estimate.

** This included all enteral, parental and respiratory/inhaled medications

Table 3. Decannulation Results

	Total (%)	Decannulated	50 th percentile of decannulation time (95% CI)	75 th percentile of decannulation time (95% CI)	P value*
Patients	426	163 (38%)	1.2 (0.9,1.5)	5.3 (3.2,∞)	
Sex	178 (42%)	67 (41%)	0.9 (0.5,1.7)	5.3 (2.5,∞)	0.66
Female	148 (58%)	96 (59%)	1.3 (1.1,2)	4.8 (3.1, ∞)	
Male					
Age at Trach	176 (41%)	83 (47%)	1.5 (1.2,2)	2.9 (2.5,4)	0.04
<1 year	102 (24%)	29 (28%)	1.8 (0.7,3)	Not-est	
1-5 Years	148 (35%)	51 (34%)	0.4 (0.3,0.7)	Not-est	
>5 years					
Tracheostomy	99 (23%)	63 (64%)	0.9 (0.7,1.3)	2.2 (1.4,2.8)	<0.000
Indication	40 (9%)	21 (52%)	0.5 (0.2,0.7)	1.9 (0.7, ∞)	1
Airway Obstruction	66 (15%)	32 (48%)	1.5 (0.9,2.3)	2.7 (2.2,4)	
Resp - Acquired	82 (19%)	30 (37%)	0.3 (0.2,1.2)	Not-est	
Resp - Congenital	139 (33%)	17 (12%)	Not-est	Not-est	
Neuro – Acquired					
Neuro - Congenital					
Oncology process					0.04
No	388 (91%)	147 (90%)	1.3 (1,1.8)	5.4 (3.2,∞)	
Yes	38 (9%)	16 (10%)	0.3 (0.2,0.8)	2.8 (0.3,∞)	
Heart disease					0.85
No	320 (75%)	118 (72%)	0.9 (0.6,1.3)	7.0 (3.2, ∞)	
Yes	106 (25%)	45 (28%)	1.8 (1.2,2.3)	4.0 (2.5,7.4)	

*Log-rank p-value comparing K-M survival curves.

Table 4. Predictors of Decannulation

	≤ 1 year post-surgery				>1 year post-surgery			
	Unadjusted		Adjusted		Unadjusted		Adjusted	
Variable	HR	95% CI	HR	95% CI	HR	95% CI	HR	95% CI
Female	1.4	0.9,2.1	1.3	0.8,2.0	0.8	0.5,1.3	0.9	0.5,1.4
Age at tracheostomy								
<1	1.0	Ref	1.0	Ref	1.0	Ref	1.0	Ref
1-5	1.9	1.0,3.6	2.0	1.0, 4.0	0.3	0.1,0.5	0.5	0.2,1.0
>5	4.1	2.4,7.1	3.7	2.0, 6.9	0.1	0.0,0.2	0.2	0.1,0.5
Indication for tracheostomy								
NC	1.0	Ref	1.0	Ref	1.0	Ref	1.0	Ref
AO	3.8	1.8,8.2	6.1	2.8, 13.3	11.9	5.5,25.6	7.3	3.3, 16.2
NA	5.9	2.8, 12.8	4.8	2.2, 10.7	2.2	0.7,6.8	2.8	0.9,3.6
RA	6.8	3.0,15.5	8.5	3.7,19.6	4.2	1.4,12.8	3.2	1.0,10.3
RC	1.9	0.7,5.0	4.2	1.6, 11.1	11.9	5.3,26.7	6.6	2.8, 15.6
Heart disease	0.3	0.1,0.6	0.3	0.2,0.7	2.2	1.4,3.4	1.1	0.7, 1.8

Oncologic process	2.7	1.5,4.9	0.5	0.1,2.0	0.5	0.1,2.0	0.6	0.1,2.5

*Cox Proportional Hazards model simultaneously adjusting for all other variables.

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Figure 1 .

Figure 2 .

Figure 3 .

Figure 4 .

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