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Factors Associated With Gastrostomy Tube Complications in Infants With Congenital Heart Disease

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Abstract

Introduction: Children with congenital heart disease (CHD) often experience feeding intolerance due to aspiration, inability to tolerate feed volume, or reflux within the first few months of life, requiring a surgically placed gastrostomy tube (GT) for durable enteral access. However, complications such as GT dislodgement, cellulitis, and leakage related to GT use are common. GT-related complications can lead to unscheduled pediatric surgery clinic or emergency room

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Author Contributions

All authors made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version submitted.

Level of Evidence

Level III.

Disclosure

None declared

Meeting Presentation

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(ER) visits, which can be time consuming for the family and increase overall healthcare costs. We sought to identify factors associated with GT complications within 2 wk after GT surgery and 1-y after discharge home following GT placement in infants with CHD.

Methods: We performed a retrospective cohort study using the Society of Thoracic Surgeons database and electronic medical records from a tertiary children's hospital. We identified infants <1 y old underwent CHD surgery followed by GT surgery between September 2013-August 2018. Demographics, pre-operative feeding regimen, comorbidities, and GT-related utilization were measured. Postoperative GT complications (e.g., GT cellulitis, leakage, dislodgement, obstruction, and granulation tissue) within 2 wk after the GT surgery and an unplanned pediatric surgery clinic or ER visit within 1-y after discharge home were captured. Bivariate comparisons and multivariable logistic regression evaluated factors associated with GT complications and unplanned clinic or ER visits. A Kaplan–Meier failure curve examined the timing of ER/clinic visits.

Results: Of 152 infants who underwent CHD then GT surgeries, 66% ($N=101$) had postoperative GT complications. Overall, 83 unscheduled clinic visits were identified after discharge, with 37% ($N=31$) due to concerns about granulation tissue. Of 137 ER visits, 48% ($N=66$) were due to accidental GT dislodgement. Infants who were hospitalized for 2 wk after GT surgery had more complications than those discharged home within 2 wk of the GT surgery (40.6% versus 15.7%, $P=0.002$). Infants receiving oral nutrition before CHD surgery (38.6% versus 60%, $P<0.001$) or with single ventricle defects (19.8% versus 37.3%, $P=0.02$) had fewer GT complications. After adjusting for type of cardiac anomaly, infants receiving oral nutrition prior to CHD surgery had a decreased likelihood of GT complications (odds ratio OR 0.46; 95% confidence intervals CI:0.23-0.93). A Kaplan–Meier failure curve demonstrated that 50% of the cohort experienced a complication leading to an unscheduled ER/clinic visit within 6 mo after discharge.

Conclusions: Unplanned visits to the ER or pediatric surgery clinic occur frequently for infants with CHD requiring a surgically placed GT. Oral feedings before cardiac surgery associated with fewer GT complications. Prolonged hospitalization associated with more GT complications. Optimizing outpatient care and family education regarding GT maintenance may reduce unscheduled visits for this high-risk, device-dependent infant population.

Keywords

Complications; Congenital heart disease; Gastrostomy tube; Infants

Introduction

Congenital heart disease (CHD) is a common birth defect with an estimated prevalence of 6.9 cases per 1000 live births in North America.^{1,2} Approximately 39-80% of infants with CHD require gastrostomy tube (GT) placement^{3,4} due to concerns for aspiration, inability to orally take the feeding volume, or poor weight gain^{5,6}. However, complications such as GT dislodgement, cellulitis, and leakage are common after hospital discharge and require unplanned pediatric surgery clinic or emergency room (ER) visits.⁷⁻¹⁰

Children with GT malfunctions and dislodgements commonly visit the ER.⁸ ER visits are costly for families caring for CHD infants who pay an average of \$1266 for these visits, whereas, families of children without CHD pay an average of \$741.¹¹ Hence, GT-related complications increase the time, medical, financial burden on the infant and family. One way to reduce these unexpected costs from complications of GTs is scheduling visits as well as setting time aside for unexpected visits to an outpatient specialty surgical clinic for families of CHD children with GTs.⁹ Surgeons have attempted to address these complications by employing alternate techniques for suturing and dressing surgical wounds.^{12,13} Despite a reduction in GT-related issues, complications still persist, including granulation tissue formation and tube dislodgement requiring ER visits.¹²

Our study aims to identify clinical factors associated with GT complications within 1-y following discharge. We sought to identify potentially modifiable clinical factors associated with GT surgery complications, such as preoperative oral feeding abilities of infants with CHD and the timing of complications. Our goal is to identify infants at highest risk for GT surgery complications to tailor long-term follow-up care both pre- and postoperatively.

Material and Methods

Setting and population

We performed a retrospective cohort study using the Society of Thoracic Surgeons database and the electronic medical record from 2014 to 2019 from a tertiary level children's hospital in Los Angeles. We enrolled infants less than 1 y of age with CHD who underwent CHD surgery followed by GT surgery between January 2014-October 2019. We excluded children who: 1) were greater than 1 y old at time of GT placement, 2) lost to follow-up, 3) had a thoracic surgery, or 4) expired during their hospitalization related to their CHD surgery (as we could not assess our primary outcome). We assessed GT complications for 1 y following discharge. The Children's Hospital Los Angeles Institutional Review Board approved this study (18-00,509) and waiver of informed consent.

Primary outcome

We defined the "GT complications" outcome dichotomously (yes *versus* no) as any complication within the 2-wk inpatient period after GT placement or an unplanned pediatric surgery clinic or ER visit related to the GT within 1 y of discharge following GT surgery. GT complications included cellulitis, leakage, obstruction, granulation tissue formation, dislodgement, and other GT related issues during the timeframes listed above.

Patient characteristics

Data abstracted included patient demographics, such as admission age at cardiac surgery, sex, race, ethnicity, insurance status, and gestational age. Cardiac operative variables included single ventricular or biventricular defects, age at cardiac surgery, type of CHD operation, cardiopulmonary bypass time (minutes), aortic cross clamp time (minutes), and total mechanical vent time (days). GT variables included percent of oral feedings consumed prior to cardiac surgery, age (days) at first oral feed attempt, nasojejun tube before a GT surgery, indication for GT placement, age at GT surgery, type of GT placed, and any

complications during their inpatient stay related to the GT placement. Variables collected upon discharge were: 1) feeding modality and 2) percent of goal feeds taken orally. Information collected after discharge were: 1) 30-d readmission related to the GT, 2) 30-d and 1-y mortality, 3) whether the patient was using the GT at 1 y postoperatively, and 4) unscheduled pediatric surgery clinic or ER visits related to the GT.

Statistical analysis

Descriptive statistics evaluated the relationship between patient characteristics and any GT complication. Chi-square and Fisher-exact tests (for categorical variables) and Wilcoxon-rank sum tests (for continuous variables) assessed associations between individual preoperative, operative, and discharge characteristics and GT complications. Multivariable logistic regression analysis analyzed clinically relevant covariates chosen a priori and by covariates with significant differences between groups ($P < 0.05$). Predictors included single ventricular defect, patient feeding orally before CHD surgery, noncardiac abnormalities, and syndrome or chromosomal abnormalities. We evaluated Akaike information criterion, negative log-likelihood, and c-statistic to select the model with the smallest values while maintaining a high c-statistic for the final model.

A Kaplan–Meier (KM) failure graph was created for unscheduled pediatric surgery clinic or emergency room (ER) visit related to GT complications within one-y. The failure graph was calculated using Stata/SE version 15.1 (StataCorp LLC, College Station, Texas). All other analyses were conducted with twosided significance, $\alpha = 0.05$. Data were analyzed using Statistical Analysis System software 9.4 (SAS Institute, Inc, Cary, North Carolina).

Results

We identified 152 infants with CHD who underwent CHD surgery followed by GT surgery (Fig. 1). We list the CHD diagnosis types in Table 1. Of those, 101 (66%) presented with a post-operative GT a GT complication (Table 2). Demographics, cardiac surgery factors and GT surgery factors did not differ between groups. Granulation tissue (37%) was the primary reason for an unscheduled clinic visit, and GT dislodgement (48%) was the most common reason for unscheduled ER visit (Table 3). Bivariate comparisons showed that continued hospitalization for greater than 2 wk after GT surgery was associated with GT complications (40.6% versus 15.7%, $P = 0.002$). Conversely, patient receiving oral feeds before undergoing cardiac surgery (38.6% versus 60%, $P = 0.01$) and infants with SV defects demonstrated fewer GT complications (19.8% vs 37.3%, $P = 0.02$) (Table 4). After adjusting for SV defect and noncardiac abnormalities, infants receiving oral feeds before cardiac surgery were significantly less likely to experience a GT complication within a year after discharge (odds ratio OR = 0.46, 95% confidence interval CI = 0.23, 0.93) (Table 5). The KM failure curve demonstrated that 25%-50% of unscheduled GT complication visits occurred between 44 and 201 d after discharge (Fig. 2).

Discussion

In summary, most infants with CHD requiring GT placement for durable enteral access experienced GT-related complications, including granulation tissue or GT dislodgement.

Approximately, half of all inpatient and ER visits related to GT complications occurred between 6 wk and 6 mo after GT placement. Infants requiring hospitalization for >2 wk after GT surgery more often had GT complications. Conversely, infants tolerating oral feedings before cardiac surgery and those with single ventricle defects had fewer GT-related complications. These findings indicate that overall clinical disease burden likely influences an infant's risk of long-term GT complications.

Like previous reports, CHD infants receiving a GT for enteral access often experience a GT complication. Goldberg et al. (2010) found granulation tissue complications in 68% of children with GTs similar to our results of 66%.⁷ On the other hand, McSweeney et al. (2013), however, found that about 11% of children within their study experienced at least one GT related complication, however, their cumulative incidence rates for complications increased to 15% by a median follow up of 5.4 y as they followed patients for 10 y after GT placement with some loss to follow-up.¹⁴ Their lower complication rate may be explained by McSweeney *et al.* investigating an older cohort of children (mean age of 22 mo) over a longer timeframe compared to our younger cohort (mean age of 3.8 mo) over a shorter period. Similarly, Landisch et al. (2016), noted that approximately, 7.6% of infants with laparoscopically placed GTs experienced tube dislodgements.¹⁵ This reduced rate of complications may be related to their short study time frame of 3 mo compared to our 1-y follow-up timeframe. Ours is the first report to utilize a KM failure curve of complications after GT placement in CHD infants, demonstrating that most clinic/ER visits occurred early following discharge.

Other investigators noted similar types of GT complications as compared to our study in which most of these complications lead to ER visits. Naiditch et al. (2010) concluded that from those children under 5 y old going to the ER for GT related complications, 58% developed granulation tissue and 28% experienced tube dislodgements. Most of this cohort received an open GT placement.¹⁶ Savaadra et al. (2009) found GT dislodgement as the leading reason for ER visits.⁸ Although, these studies did not address clinical factors associated with GTs, they confirmed similar GT complications rates and thus costly burden of these ER visits¹⁷ providing further support for the need of family resources to provide cost-effective care. Of note, most of these expenses do not incorporate the lost income and time parents and caretakers of children with CHD also experience.

Infants tolerating oral feedings before CHD surgery demonstrated fewer GT-associated complications. Previous studies reported that infants with CHD who fed orally had decreased length of hospitalizations compared to those with GTs.¹⁸ It is reasonable that the infants with CHD who fed orally may be more clinically stable and thus may have had shorter hospital stays, fewer complications, and heals sooner from their surgeries. Since those infants fed before their GT surgery, they may have had more practice feeding orally or had better oral feeding skills initially than those infants with more complications and thus, were able to fully eat by mouth sooner, leading to a shorter time of using the GT, and therefore less complications.

Interestingly, infants in the present study with single ventricle cardiac defects experienced fewer GT complications. These findings were somewhat counter-intuitive as infants with

single ventricle defects require more complex cardiac surgery and are generally considered more critically ill, and often experience increased medical complications.¹⁹ Our findings may be institutionally dependent. These infants with single ventricle defects were seen in our outpatient cardiology clinics and other subspecialty clinics more frequently after discharge because of their higher acuity. More frequent opportunities to interface with the healthcare team may have indirectly contributed to fewer unscheduled ER visits for GT complications as these complications may have been identified and treated sooner in outpatient clinics. Since a large proportion of the GT complications (25-50%) occur between the 6 wk to 6 mo timeframe, scheduled clinic visits during that period may decrease unnecessary ER visits, especially in high-risk infants like those with SV heart defects.^{20,21}

Our study had several limitations. First, our retrospective study relied on medical record documentation and could not control for outcome variables in a standardized fashion. Nevertheless, our outcomes of interest were all part of standards of care for the assessment of GTs. Moreover, we did not have missing data for any of our patients regarding their GT or other issues in which they went to clinic or the ER visits. Furthermore, our study did not capture visits that occur outside of our institution. However, most of these patients had complex CHD and transferred to our institution for further management given the need for multidisciplinary care that other local hospitals do not offer. Next, we did not have a control group for comparison, so it is unclear if infants without CHD who have GTs would have similar complication rates. The literature, however, in children with CHD (referred to above) demonstrated GT complication levels similar to our study's findings. Lastly, our study may only be generalizable to CHD infants at our institution. We are a tertiary center and see the most critically-ill infants with CHD, which may limit generalizability of our findings.

Conclusions

Infants with CHD commonly have GT-related complications, with approximately, 25% resulting in an unscheduled clinic or ER visit within 60-d of hospital discharge. Infants receiving oral feedings before cardiac surgery and infants with single ventricle physiology are less likely to experience complications. Thus, closer follow-up with the healthcare team may reduce GT complications. Another possible strategy to decrease GT-related complications is improved maintenance through enhanced family education regarding GT care and maintenance for high-risk CHD infants. Quality improvement efforts to optimize family education regarding GT care and management and increased follow-up may decrease the need for unplanned clinic/ER visits related to GTs and therefore, decrease health care costs in this device dependent population.

Availability of Data

Available upon request.

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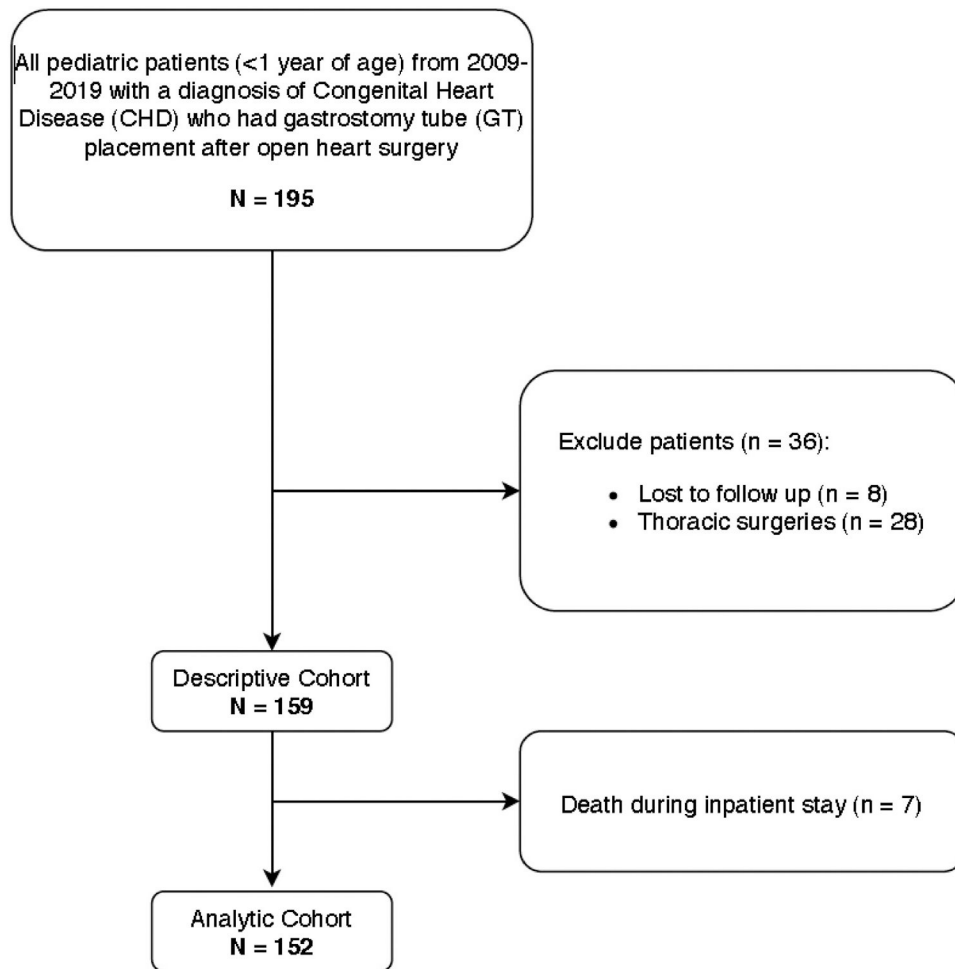


Fig. 1 –
Flow diagram for cohort selection.

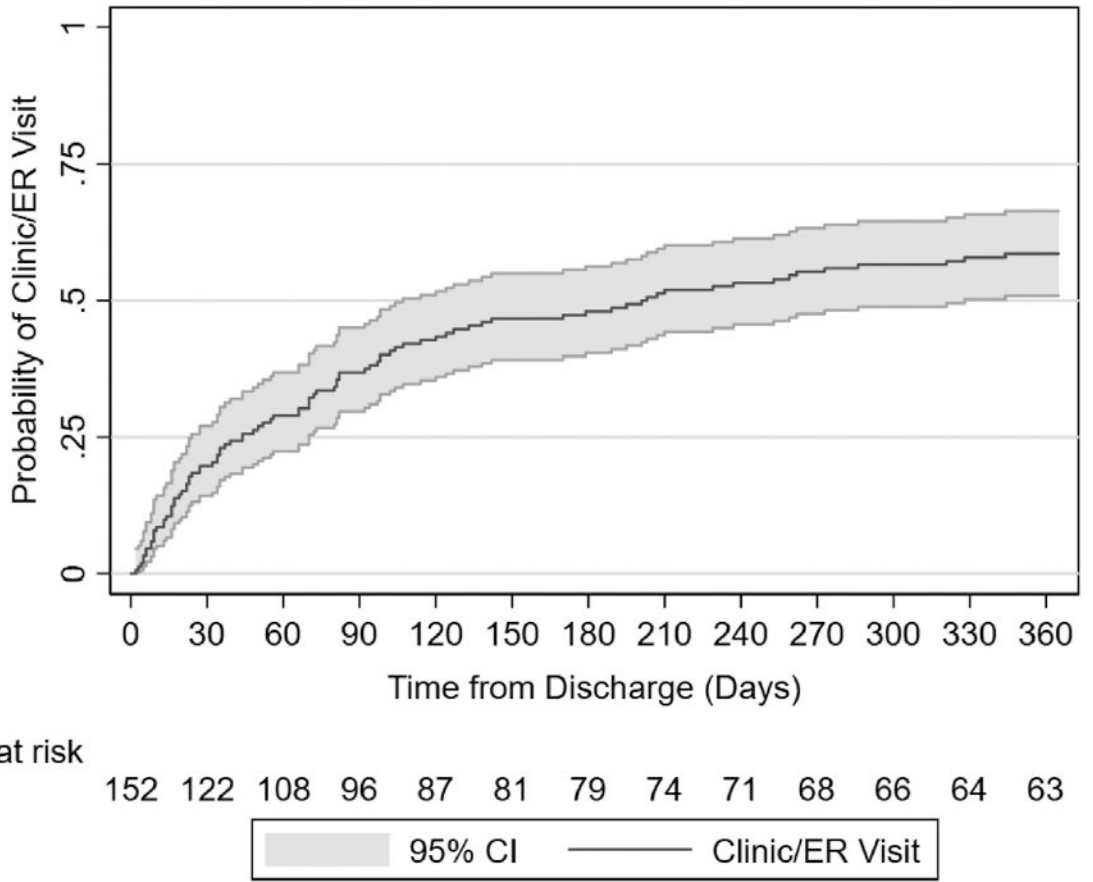


Fig. 2 -. Kaplan–Meier Failure Curve of unscheduled pediatric surgery clinic or emergency room (ER) visit related to gastrostomy tube complications and the number of infants at risk at each time point.

Table 1 –

List of the types of Congenital Heart Defects in study subjects.

Defect type	N = 152	%
Aortic Arch Hypoplasia or Coarctation of the Aorta	16	11
Atrial Septal defect	2	1
Atrioventricular Septal defect	10	7
Double Chambered Right ventricle	1	2
L-Transposition of the great Arteries	3	7
Double Outlet Right ventricle	11	7
Hypoplastic Left heart syndrome	10	3
Interrupted aortic Arch	5	1
Mitral Valve Disease/Stenosis	2	2
Hemitruncus (Anomalous origin of right pulmonary artery from aorta)	1	1
Pulmonary Atresia with Intact ventricular Septum	3	3
Pulmonary Atresia with ventricular Septal defect	2	1
Pulmonary Stenosis	4	14
Shone's syndrome	2	12
Other single ventricle physiology	21	5
Tetralogy of Fallot	18	4
D-Transposition of the great Arteries	7	1
Total Anomalous Pulmonary Venous Connection	6	1
Ebstein's anomaly	2	16
Vascular Ring	2	11
Ventricular Septal defect	24	1

Table 2 – Bivariate comparisons of cohort demographics for any complication within a year of gastrostomy tube (GT) surgery.

Demographics	No complication N = 51 (34%)		Complication N = 101 (66%)		P-value
	N	(%)	N	(%)	
Demographics					
Female sex	24	47.1	49	48.5	0.9
White race	12	23.5	20	19.8	0.6
Hispanic ethnicity	32	62.8	66	65.4	0.8
Public insurance	34	66.7	78	77.2	0.2
Syndromic or chromosomal abnormalities	27	52.9	54	53.5	1.0
	Median	IQR	Median	IQR	
Gestational age, weeks	37.0	36.0-39.0	38.0	36.0-38.0	0.9
Age (days) at first oral attempt	23.0	3.0-45.0	16.0	2.0-37.0	0.2
Cardiac operative variables					
Cardiopulmonary bypass (CPB) during heart surgery	44	86.3	89	88.1	0.7
CPB time, minutes (mean SD)	67.7	47.3	66.5	43.9	0.8
GT operative variables					
Indication for GT - poor oral intake	41	80.4	70	69.3	0.1
GT surgery type- open	16	31.4	39	38.6	0.6
	Median	IQR	Median	IQR	
Age (days) at GT placement	85.0	51.0-166.0	80.0	49.0-126.0	0.9
Total percent of goal oral feeding tolerated before GT	0.0	0.0-11.6	0.0	0.0-8.0	0.6
Outpatient variables					
GT use at 1-y	35	68.6	74	73.3	0.9

Table 3 –

Reasons for unscheduled clinic or emergency room (ER) visits due to gastrostomy tube (GT) complication.

Demographics	Visit type			
	Clinic		ER	
	<i>N</i> = 83		<i>N</i> = 137	
	<i>N</i>	%	<i>N</i>	%
GT cellulitis	12	14.5	17	12.4
GT leakage	21	25.3	21	15.3
GT obstruction	1	1.2	1	0.7
GT granulation tissue	31	37.3	4	2.9
GT falling out	12	14.5	66	48.2
Other	6	7.2	28	20.4

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Table 4 – Clinical factors correlated with gastrostomy tube (GT) complications within a year.

Demographics	No complications		Complications		P-value
	N	%	N	%	
Patient received oral feeds before cardiac surgery	31	60.8	39	38.6	0.01
Single ventricular defect	19	37.25	20	19.8	0.02
Remained inpatient >2 wk after GT surgery	8	15.7	41	40.6	0.001
Age at time of cardiac surgery (days)	48.6	66.5	77.6	94.0	0.05
Total mechanical vent time (days)	21.7	19.7	21.1	27.2	0.06

Table 5 –

Multivariable logistic regression of factors associated with gastrostomy tube (GT) complications in infants who received oral feeds before GT surgery *versus* not adjusted for single *versus* biventricular CHD and noncardiac abnormalities.

Demographics	OR	95% CI	
Single ventricular defect	0.49	0.23	1.06
Patient received oral feeds before cardiac surgery	0.46	0.23	0.93
Non-cardiac abnormalities	0.96	0.48	1.94

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