



Predictors of multiple readmissions or death in the first year after Nissen fundoplication in children

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Accepted: 10 December 2018 / Published online: 17 December 2018
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Abstract

Purpose Nissen fundoplication (NF) is commonly performed in children with gastro-esophageal reflux disease (GERD). Patients undergoing NF often have co-morbidities. Reported outcomes of NF vary considerably. This study investigated which factors might predict multiple readmissions or death in the first year following NF at our institution.

Methods A retrospective chart review of 187 children who underwent NF at our institution between January 2004 and December 2015 was undertaken. Underlying medical conditions, age, weight, presence of malnutrition, length of hospital stay prior to surgery and type of surgery were recorded. Patients who had more than one admission in the first post-operative year were compared to those who had one or none, and patients who died within the first post-operative year were compared to those who did not.

Results Risk factors for multiple readmissions were underlying cardiac disease ($p=0.011$), esophageal atresia (EA) ($p=0.011$), and esophageal stricture ($p=0.0002$). Risk factors for death included younger age ($p=0.028$), need for gastrostomy tube (GT) ($p=0.01$) and prolonged pre-operative hospital admission ($p=0.0003$).

Conclusion This study identified multiple factors associated with readmission and death in the first year after NF. These findings will help with the counseling patients and caregivers regarding expectations following NF.

Keywords GERD · Nissen · Fundoplication · Readmission · Mortality

Introduction

At the Red Cross War Memorial Children's Hospital in South Africa, the procedure of choice for children with proven gastro-esophageal reflux (GER) with complications such as recurrent respiratory infections, chronic lung disease, failure to thrive, or esophageal strictures—is Nissen fundoplication (NF). At this institution, NF is also performed in children requiring gastrostomy tube (GT) who demonstrate moderate–severe GER on pre-operative work-up.

The majority of children undergoing NF have significant medical co-morbidities, frequently necessitating multiple or prolonged hospital admissions. In performing NF, the goal is to optimize feeding (in the case of children undergoing GT placement), and to minimize the symptoms and complications of GER or GERD, and by extension to reduce the time spent in hospital for these children and their caregivers. A number of children will, however, require multiple readmissions to hospital after surgery, and a proportion of children will die in the years following NF.

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A retrospective chart review was undertaken, with the goal of establishing which factors predict a need for multiple hospital readmissions or death in the first year after NF at our institution. Prior to the study, we noted that many of the parents, as well as the referring clinicians were under the impression that this procedure would result in imminent and sustained discharge of the patient. Although the morbidity associated with NF itself is low, this procedure may not necessarily eliminate the need for hospital admissions or prolong life in children with other serious illnesses. The purpose of this study was to help the surgical team counsel patients, their caregivers and their treating clinicians regarding their expectations in the first year after surgery.

Methods

After obtaining approval from the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (reference number HREC 474/206), a retrospective chart review of patients undergoing anti-reflux surgery at RCWMCH was conducted. All patients who underwent anti-reflux surgery between January 2004 and December 2015 were considered. A total of 348 patients were identified as having undergone NF in this time. All medical records at this institution are currently still in paper format. Patients whose charts could not be located by the hospital records department or whose notes had significant sections missing ($n = 149$), who underwent their first anti-reflux procedure at a different institution or prior to January 2004 ($n = 3$), and who were lost to follow-up before 1 year were excluded ($n = 9$). This left a study sample of 187 patients.

Tests used in the work-up for GER included contrast swallow ($n = 176$; 94%) ‘milk scan’ scintigraphy ($n = 145$; 78%), and endoscopy ($n = 25$; 13%). Contrast swallow was predominantly used as an adjunct to interrogate patients’ swallowing mechanisms in patients who clinically had evidence of an ‘unsafe swallow’ on assessment by a speech and language therapist, and to define gastric anatomy. ‘Milk scan’ scintigraphy was considered positive for GER if a milk feed labeled with technetium 99-m sulfur colloid displayed moderate–severe reflux into the esophagus on dynamic imaging over a 30-min study period, as determined by institutional protocol [1]. Because of resource and technical limitations in our setting, pH-MII is seldom performed at this institution. Milk scan scintigraphy is performed instead, and the sensitivity and specificity of this study as compared to pH-MII is reviewed in reference [1]. Endoscopy was considered positive for GER if biopsy of the distal esophagus demonstrated histological features typical of reflux esophagitis, in a patient with suggestive symptoms. All patients who underwent NF had a positive finding for GER on at least one of these investigations.

Data regarding patient demographics, nutritional status, place of residence, underlying medical conditions, previous surgery, anti-reflux surgery technique and post-operative course were captured. Patients were classified as malnourished if their expected weight-for-height or weight-for-sex was below the 10th centile, if there was a drop-off or plateau in their weight over a 2-month period prior to the surgery, or if there was evidence of stunting with a height of less than 90% of the expected height-for-age. Patients who had more than one hospital admission in the first post-operative year were then compared to those who had one or no admissions, and patients who died within the first post-operative year were compared to those who did not. Nonparametric Mann–Whitney U tests were used for numerical variable analysis. Chi-squared test for independence was used to compare the counts of nominal categorical variables.

Due to the retrospective nature of the study, there were no consent requirements. Strict confidentiality was maintained by removing patient identifiers and keeping data in password protected databases on a password-protected computer. The Division of Paediatric Surgery covered all expenses related to the study. The authors declare no conflict of interest.

Results

Of the 187 patients included in the review, 105 (54%) were male. The mean age at the time of surgery was 36 (1–182) months, and the mean weight was 9.9 kg (2.3–46). One hundred thirty-seven (73%) patients were malnourished. Underlying medical conditions, previous surgeries and GERD-symptoms can be seen in Table 1. Only 7 (4%) of patients had no identifiable underlying conditions, apart from GERD. The most common underlying pathology was a central nervous system disorder ($n = 110$, 59%), followed by neuromuscular disorders ($n = 42$, 23%), established chronic lung disease ($n = 38$; 20%) and cardiac disease ($n = 31$; 17%). Sixty-four (34%) patients had had previous non-gastric or esophageal surgery, the most common of which was head and neck surgery (usually tracheostomy) in 27 (14%) patients. Five (3%) patients had EA and 8 (4%) had esophageal strictures. One hundred forty two patients (71%) required gastrostomy, which was the primary indication for surgery. In 20 (14%) of these patients, GT was already in situ at the time of NF, having been placed at an outside institution or after initial work-up for GER was negative.

One hundred twelve (59%) funduplications were performed laparoscopically, 72 (38%) were performed via laparotomy, and in three cases (2%) the surgery was started laparoscopically and the surgeon then converted to an open procedure.

Mean time to full feeds post-operatively, either orally or via gastrostomy, was 5 days (0–30). In most patients, feeds

Table 1 Underlying medical conditions, previous surgeries and symptoms prompting investigation in patients undergoing Nissen fundoplication

	<i>N</i>	%
Underlying medical conditions		
CNS disorder (congenital or acquired)	110	59
Neuromuscular disorder	42	23
Established CLD	38	20
Cardiac disease	31	17
Genetic abnormality	30	16
Prematurity	23	12
Tuberculosis	21	11
Endocrinopathy	14	8
Immune compromise	11	6
Esophageal stricture	8	4
EA/Congenital TEF	5	3
Cystic fibrosis	3	2
Congenital intestinal abnormalities	2	1
Acquired TEF	1	0.5
Other	36	19
None apparent	7	4
Previous surgeries		
Head and neck	27	14
Gastrostomy	18	10
Cardiac	17	9
Orthopaedic and minor procedures	17	9
Abdominal, pelvic and perineal surgery	10	5
Dilation of esophageal stricture	11	6
Repair of TEF/EA	5	3
Thoracic excluding cardiac	1	0.5
None recorded	123	66
Symptoms prompting investigation		
Recurrent respiratory tract infections	108	56
Aspiration	87	45
Vomiting	68	35
Ineffectual feeding	51	27
Coughing	51	27
Unsafe swallow	34	18
Dysphagia	9	5

CNS central nervous system, *EA* esophageal atresia, *TEF* tracheo-esophageal fistula, *CLD* chronic lung disease

were incrementally increased by one-third each day post-surgery, allowing most patients to be on full feeds by Day 4 post-op. Mean time to discharge for the whole group was 18 days (1–368), but of note is the fact that patients who were admitted for surgery from home had a mean post-operative length of stay (LOS) of 11 days, whilst those who had been in-hospital for more than a month had a mean post-operative LOS of 19 days, and those who had been in-hospital for their entire lives had a mean post-operative LOS of 48 days (Fig. 1).

Predictors of multiple readmissions in the first post-operative year

Fifty-five (29%) patients were admitted more than once in the first post-operative year. In this group, the mean number of readmissions in the first year after surgery was 4 (2–14) and the mean time to the first readmission was 11 weeks (1–51). The most common indications for readmission were treatment of lower respiratory tract infections ($n=37$; 67%), issues related to premorbid conditions ($n=19$; 33%), and endoscopic management of esophageal strictures ($n=9$; 16%).

Variables associated with multiple readmissions in the first post-operative year (Table 2) were underlying cardiac disease ($p=0.011$), EA ($I=0.011$), and esophageal stricture ($p=0.0002$). Of the 31 patients in this group who had underlying cardiac disease, 8 (26%) required readmission for issues related to their cardiac disease, and 3 (10%) for staged cardiac surgery. The type of surgery the patient underwent (laparoscopy vs laparotomy) was not a significant contributor to multiple readmissions.

Of the 55 patients with multiple readmissions in the first post-operative year, 30 (55%) were reinvestigated for GERD. Of these, 15 (50%) had no evidence of GER, and 5 (9%) had esophageal strictures with no GER (these patients had esophageal stricture disease prior to NF). The remaining 10 (18%) had evidence of moderate–severe GER on contrast swallow ($n=5$), milk scan ($n=5$), histological specimens taken during endoscopy ($n=3$) or a combination of the above. Three (30%) patients with a positive finding for GER were also shown to have a migrated or slipped wrap.

Ultimately, 5 patients (9%) in the multiple-readmission group underwent redo fundoplication (1 of these patients had two redo surgeries). Of the entire study group, 14 (8%) of patients required redo surgery from the start of the study period to the time of writing.

Predictors of death within a year of NF

Fifteen (8%) patients died within a year of NF. Of these, 4 (2%) patients died during the same hospital admission as their surgery. Mean time to death was 15 weeks (3–42) weeks. Cause of death was severe sepsis of respiratory origin in 5 patients, was due to the sequelae of pre-existing morbidity in 5 patients, and was due to aspiration in 1 patient. The patient who died of aspiration had a GT, but it was not clear whether or not this patient had been fed orally prior to their demise. In four patients the cause of death is not known. Of these patients, 9 died at our facility, 4 died at home in the care of their families, 2 died at a hospice facility, and 1 died at another hospital.

Variables associated with death within a year of surgery are listed in Table 3. Significant variables were younger age at the

Fig. 1 Mean post-operative length of stay compared to place of residence prior to surgery

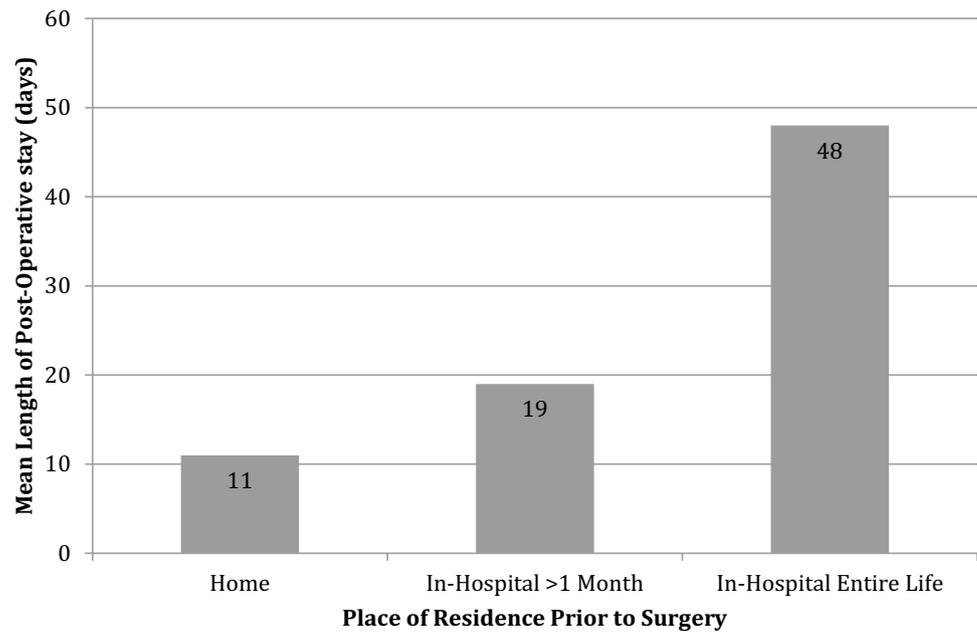


Table 2 Variables associated with multiple readmissions within the first post-operative year

Variable	<i>n</i> (total = 55/187)	Statistic	<i>p</i>
Age	Mean = 28 months (vs 39 months)	$Z = 4124.5$	0.142
Weight	Mean = 8.9 kg (vs 10.3 kg)	$Z = 3537.0$	0.32
In-hospital > 1 month or entire life before surgery	25	$\chi^2 = 3.73$	0.44
Malnutrition	40	$\chi^2 = 0.09$	0.75
Need for GT	41	$\chi^2 = 2.97$	0.08
Underlying medical conditions			
CNS	28	$\chi^2 = 2.01$	0.155
Neuromuscular	10	$\chi^2 = 0.82$	0.36
Cardiac	15	$\chi^2 = 6.44$	0.011
CLD	13	$\chi^2 = 0.53$	0.46
Immune deficiency	4	$\chi^2 = 0.27$	0.60
Prematurity	4	$\chi^2 = 1.82$	0.17
Genetic abnormality	11	$\chi^2 = 0.91$	0.34
Congenital TEF	4	$\chi^2 = 6.33$	0.01
Esophageal stricture	7	$\chi^2 = 13.5$	< 0.001

Bold values represent those that achieved statistical significance

Statistics: Z score determined by Mann–Whitney U test and χ^2 determined by Chi-squared test for independence

time of surgery, as well as a prolonged pre-surgery hospital admission. Patients who died within a year of surgery were operated at a mean age of 28 (3–182) months, compared to those who were alive at 1 year post-surgery who were operated at a mean age of 37 (1–165) months ($p = 0.028$). Admission to hospital for more than a month, or for the patient's entire life, was an independent risk factor for death within the first post-operative year ($p = 0.0003$). The need for gastrostomy was also an independent risk factor for death within the first

post-operative year ($p = 0.01$). No specific underlying medical conditions had a statistically significant association with mortality in the first post-operative year.

Table 3 Variables associated with death within the first post-operative year

Variable	<i>n</i> (total = 15/187)	Statistic	<i>p</i>
Age	Mean = 28 months (vs 37 months)	Z = 848.0	0.028
Weight	Mean = 7.3 kg (vs 10.1 kg)	Z = 728.0	0.065
In-hospital > 1 month or entire life before surgery	11	$\chi^2 = 18.66$	0.0003
Malnutrition	12	$\chi^2 = 0.11$	0.73
Need for GT	142	$\chi^2 = 6.32$	0.01
Underlying medical conditions			
CNS	8	$\chi^2 = 1.44$	0.23
Neuromuscular	2	$\chi^2 = 1.57$	0.21
Cardiac	4	$\chi^2 = 0.23$	0.62
CLD	4	$\chi^2 = 0.13$	0.72
Prematurity	1	$\chi^2 = 0.02$	0.87
Genetic abnormality	4	$\chi^2 = 0.008$	0.9

Bold values represent those that achieved statistical significance

Statistics: Z score determined by Mann–Whitney *U* test and $\times 2$ determined by Chi-squared test for independence

Discussion

Anti-reflux surgery is frequently performed at pediatric surgical centers. Many children undergoing this surgery have co-morbidities, and the combination of an ‘unsafe’ or incoordinate swallow (which allows feeds and secretions to enter the airway) and GER results in significant symptoms and disease. The care of children with serious co-morbidities, particularly those with neurological impairment, is exhausting and stressful for parents, and severely affects the structure and organization of their lives [2]. Acute health issues are often ‘intense and urgent’, and frequent travel to hospital is difficult and disruptive [2]. The goal of NF, often in combination with the placement of a gastrostomy tube, is to allow optimum nutrient delivery whilst minimizing the risk of GER, aspiration and the consequences thereof. Ideally, surgery should enable the patient to be discharged into the care of the family or an appropriate care facility, and minimize the need to return to hospital for admissions related to GERD.

The outcomes of anti-reflux surgery vary greatly in the literature, and there is lack of homogeneity in terms of how these outcomes are described. Many studies use the need for redo surgery to quantify success rates [3], whilst others look at patient and caregiver satisfaction [2]. Some studies measure post-operative outcomes by examining how many patients are able to wean from medications such as proton-pump inhibitors [4], oral and inhaled steroids and

beta-2-mimetics [5], which are required to manage symptoms sometimes presumed to arise from GERD. Several studies compare numbers of pre- and post-operative admissions [6]. Many studies report favorable outcomes from NF. These outcomes include high rates of weaning from medications [5], decreased vomiting, decreased GI bleeding [7] and improvement in other symptoms [8], improved indices on pH monitoring [7, 8], improved quality of life [2], and a decreased need for hospital admissions [6]. However, despite the fact that many children who undergo fundoplication appear to benefit from surgery, a large proportion have ongoing symptoms [4, 9, 10] and still require numerous hospital admissions [10–12]. Many children will have ongoing needs for anti-reflux medication [4], will have multiple post-operative lower respiratory tract infections (LRTI) [6, 7, 10], and failure to thrive [10]. Reported mortality rates in patients who have undergone anti-reflux surgery range from 3.8 to 38%. Death is usually a result of these patients’ co-morbidities [4, 7–10, 12–14].

In this series, around one-third of children undergoing NF required more than one admission in their first post-operative year, and mortality was 8% at 1 year post-surgery. The goal of this study was to determine whether or not there were any predisposing factors that would allow clinicians to predict which patients may die or require multiple readmissions within the first post-operative year, to improve counseling and better manage the expectations of patients undergoing NF, and their caregivers.

In this patient population, underlying cardiac disease, and esophageal pathology in the form of EA or esophageal stricture were independent risk factors for multiple readmissions. Regarding patients with esophageal pathology, these recurrent admissions were not unexpected as they were required for repeated stricture dilation, which was the third most common indication for repeat admissions in the multiple readmissions group. The effects of fundoplication in children with esophageal atresia remain dubious, with high reported rates of wrap failure and ongoing symptoms [15]. The need for multiple dilations after fundoplication in children with GORD-related esophageal strictures has been well described [16, 17]. Underlying cardiac disease has been identified as a risk factor for morbidity [18] and death [13] in patients undergoing anti-reflux surgery. Numerous studies point to neurologic impairment as a risk factor for ongoing symptoms, need for readmissions and episodes of LRTI [4, 6–8, 10, 12, 19] but CNS abnormalities did not achieve statistical significance as a risk factor in this series. The finding that surgical technique (open vs laparoscopic) had no bearing on need for readmissions is in keeping with the literature that finds that laparoscopic NF is not inferior to open surgery in terms of outcomes [3, 13, 19, 20].

The most striking risk factor for death within the first post-operative year in this series was a prolonged

pre-operative hospital admission. Almost three quarters of the patients who died within a year of surgery had been in hospital for more than a month, or for their entire life, at the time of operation. Related to this is the finding that children with a prolonged pre-operative in-hospital admission had a longer post-operative stay reflecting the severity of their underlying medical co-morbidities, and how the NF is usually just one therapeutic intervention of many required to get these children well enough to go home. Need for GT was also a risk factor for death (although, interestingly, not a risk factor for readmission). These findings likely reflect the severity of underlying disease in the patients who demised within a year after surgery, and the fact that NF is just one of many therapeutic interventions these children require in the attempt to make them well enough to go home. Once the NF is done, they may still require prolonged in-hospital care related to their co-morbidities, or succumb to them.

A younger age at time of surgery was also a risk factor for early mortality, which is in keeping with findings from other studies [21]. No patients died as a direct result of surgery, which is also in keeping with other literature [3, 7, 10, 11, 13].

Limitations

The greatest limitation to this study is that it was a retrospective audit, and the outcomes measured were based on medical records and chart notes. Because of this, it was not possible to standardize the measurement of outcomes, or measure subjective outcomes such as patient and caregiver satisfaction. Although it is known that a large number of patients require readmission in the first post-operative year, it can only be assumed that this is frustrating or disappointing for patients and their caregivers. It could not be established from this audit, whether or not patients and caregivers felt that NF impacted their quality of life or altered their symptomatology, and whether or not they felt that the surgery had been worthwhile.

A further limitation is the fact that 45% of patients with multiple readmissions due to respiratory symptoms in the first post-operative year were not reinvestigated for GER. Patients with respiratory symptoms are primarily admitted via pediatric medicine, and the decision to reinvestigate for GER is at the discretion of these clinicians. In the patients not reinvestigated, their respiratory symptoms were deemed to be secondary to another cause (such as aspiration after an inappropriate feed, or established chronic lung disease), but we cannot be certain that these patients did not have wrap failure.

Finally, medical records at this institution are kept in paper format. A number of records had been moved to a storage facility outside of the hospital premises, and could not be retrieved from there. Furthermore, a number of charts

had significant sections missing. This affected the sample size, and possibly the outcomes.

Conclusion

NF is a commonly performed procedure at RCWMCH. The vast majority of children undergoing this surgery have serious co-morbidities. A significant number of these children will require multiple readmissions in the first year after surgery, and some will die. These findings may help clinicians to counsel patients and their caregivers regarding the likely need for readmissions following surgery, and to try to manage their expectations.

Funding No funding was sought or received for this study.

Compliance with ethical standards

Conflict of interest There are no conflicts of interest to declare.

Ethical approval No procedures were performed on humans for the purposes of this review. Rather, we retrospectively reviewed outcomes in patients who had medically indicated procedures. Approval for this study was obtained from the Human Research Ethics Committee at the University of Cape Town Faculty of Health Sciences (reference number HREC 474/206) As such, this study was in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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