

Laparoscopic Nissen Fundoplication for Improved Gastrointestinal Symptoms and Quality of Life

D Dan¹, S Seetahal¹, V Naraynsingh²

ABSTRACT

Objective: The purpose of this study was to establish baseline data for a procedure that has yet to be defined within a Caribbean population. Using a specifically designed postoperative questionnaire, symptomatology and quality of life were assessed before and after laparoscopic Nissen fundoplication.

Methods: Twenty-three consecutive patients of the same surgeon were identified. The questionnaires measured the symptoms and social and emotional functioning, assigning each a score for comparative purposes. The cumulative score was considered the ultimate index of overall quality of life. Wilcoxon matched pairs test was used to analyse the data.

Results: The mean age of the patients was 47.5 years. There were 21 females and 2 males. Heartburn (78.3%) and regurgitation (60.8%) were the main symptoms. Postoperatively, these decreased to 17.3% and 4.3% respectively, with significant declines in other complaints such as dysphagia and nausea. The social and emotional functioning score had an average of 13.2 preoperatively; this increased to 18.3, postoperatively, out of a possible maximum of 20. None of the procedures had to be converted to open laparotomy and mean operating time was 108 minutes. Mean follow-up time was 9.7 months.

Conclusion: Laparoscopic Nissen fundoplication does provide significant improvement in overall quality of life among patients with gastrointestinal symptoms and can be performed effectively within a Caribbean setting.

Funduplicación Laparoscópica de Nissen para Mejorar los Síntomas Gastrointestinales y la Calidad de Vida

D Dan¹, S Seetahal¹, V Naraynsingh²

RESUMEN

Objetivo: El propósito de este estudio fue establecer los datos básicos para un procedimiento que tiene que ser definido todavía en el contexto de una población caribeña. Usando una encuesta postoperatoria específicamente diseñada, la sintomatología y la calidad de vida fueron evaluadas antes y después de la funduplicación laparoscópica de Nissen.

Métodos: Se identificaron veintitrés pacientes consecutivos del mismo cirujano. Las encuestas midieron los síntomas así como el funcionamiento social y emocional, asignando a cada uno una puntuación a fin de establecer comparaciones. La puntuación acumulativa fue considerada el índice final de la calidad general de vida. La prueba de pares equiparados de Wilcoxon se usó para analizar los datos.

Resultados: La edad promedio de los pacientes (21 hembras y 2 varones) fue 47.5 años. La acidez estomacal (78.3%) y la regurgitación (60.8%) fueron los síntomas principales. Postoperatoriamente, éstos disminuyeron a 17.3% y 4.3% respectivamente, con disminuciones significativas en el caso de otras dolencias, tales como la disfagia y la náusea. La puntuación del funcionamiento social y emocional tuvo un promedio de 13.2 preoperatoriamente. Este aumentó a 18.3 postoperatoriamente, de un máximo posible de 20. Ninguno de los procedimientos tuvo que ser convertido a laparotomía abierta y el tiempo promedio de operación fue de 108 minutos. El tiempo promedio de seguimiento fue de 9.7 meses.

From: ¹Department of Surgery, San Fernando General Hospital and ²Department of Surgery, The University of the West Indies, St Augustine, Trinidad and Tobago, West Indies.

Correspondence: Dr D Dan, 26 London Street, St Joseph Village, San Fernando, Trinidad and Tobago. Fax: (868)657-5951, e-mail address: dilipdan@hotmail.com

Conclusión: *La funduplicación laparoscópica de Nissen proporciona un mejoramiento significativo de la calidad general de vida entre los pacientes con síntomas GI y puede realizarse de modo efectivo en un contexto caribeño.*

West Indian Med J 2009; 58 (1): 9

INTRODUCTION

Within the Caribbean, symptomatic Gastroesophageal Reflux Disease (GERD) shows a ubiquitous prevalence and continues to be a relatively undertreated entity. It can be caused by either oversecretion of gastric acid, with subsequent reflux dynamics and/or inadequate cardiac sphincter function. Resultant symptoms include heartburn, dysphagia, weight loss and regurgitation. While hypersecretion of gastric acid can be controlled with pharmacotherapy and lifestyle modification, sphincter dysfunction is best corrected with surgical intervention. Nissen fundoplication has been shown to be an effective method of palliating symptoms, with subsequent improvement in overall quality of life (1). Traditionally, this procedure has been performed *via* an open approach but laparoscopic techniques have been on the increase. There has been no published data regarding laparoscopic Nissen procedures in the Caribbean, a situation this study seeks to redress.

Symptoms of GERD are varied and affect quality of life (QOL) both by the physical discomfort imposed, as well as by impairing the individual's ability to function on a daily basis. In many cases, this inability to function at an optimum level is the chief concern among patients seeking treatment. To measure the overall QOL among GERD patients and how this was affected by the Nissen procedure, we devised a special questionnaire that is adapted from QOL studies done in North American populations (1–7).

SUBJECTS AND METHODS

The patients selected for this study were 24 consecutive patients scheduled for laparoscopic Nissen fundoplication by the senior author. Of these, 24 completed the preoperative questionnaire and 23 the postoperative. The 24th patient suffered an unfortunate event. Though discharged two days after surgery, she returned with sudden abdominal pain and died at emergency laparotomy for postoperative haemorrhage. The mean age of the patients participating in the study was 47.5 years, ranging from 12 to 69 years. There were 21 females. All patients had been previously on proton pump inhibitors, and because of failed medical treatment were referred for surgery by their gastroenterologists. All but one had undergone endoscopy prior to surgery and all were symptomatic with a mean duration of symptoms of 2.7 years. Manometry and pH probes were done in only two patients (in the USA) as these procedures were not available locally. The study was approved by the Ethics Committee of the San Fernando General Hospital.

All procedures were done laparoscopically by the senior author; none was converted to open. During the

procedure five ports are used. The oesophageal hiatus was first exposed with reduction of any hiatal hernia that might be present. Crural dissection was done beginning with the right crus, the anterior crural confluence and then the left crus. This allowed for circumferential mobilization of the oesophagus which can be retracted anteriorly for increased operating room. Care was taken to avoid damaging the vagi. The short gastric vessels were divided with the harmonic scalpel and the fundus of the stomach mobilized. The oesophagus was dissected to provide the maximal intra-abdominal length and then the hiatus was closed using 0-Ethibond figure-of-eight sutures. Calibration of the hiatal closure was estimated and a snug fit of the oesophagus in the hiatus was ensured. The actual plication of the fundus around the oesophagus was performed with 2–0 silk sutures using its anterior and posterior walls. A 360 degree posterior floppy wrap was done in all cases. Throughout the entire procedure, care was taken to avoid damage to any vagal branches. The operation, as described, was similar to that in most modern surgical texts (8).

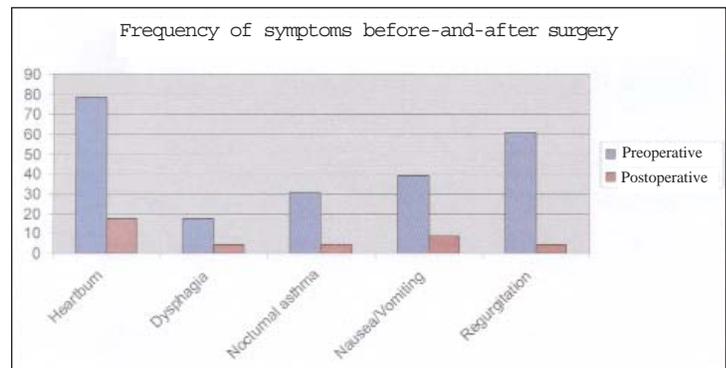


Fig. 1: Improvement trends among the major symptoms of GERD following surgery.

The mean intra-operative duration was 108 minutes (90 to 140 minutes) with a mean postoperative hospital stay of 1.2 days.

The patients were assessed preoperatively based on their symptoms and social/emotional functioning. The questionnaire was constructed to include the symptoms commonly associated with GERD (5), as well as indices indicative of daily functioning and QOL. The postoperative interviews were conducted via telephone at a mean time of 9.7 months (range 1–33 months). Symptoms were scored according to their frequency on a scale of 0 to 4. With 0 representing 'more than once daily' and 4 representing 'never'; a lower score reflected a higher frequency of symptoms. Social and emotional functioning was also scored on a 0 to 4 scale. With 0 representing 'least desirable' and 4

representing 'most desirable'; a higher score reflected a higher degree of satisfaction. Enquiries ranged from coping with daily activities to physical strength. The questionnaires also contained information about preoperative investigations, pre- and postoperative medications and need for selective food restriction before-and-after surgery.

Heartburn was the most common preoperative symptom with a frequency of 78.3%. Regurgitation (60.8%), vomiting/nausea (39.1%), nocturnal asthma (30.4%) and dysphagia (17.3%) were other common presentations. Social

than 0.05. All data totals were calculated with p values of < 0.001 and thus were shown to be statistically significant.

RESULTS

Postoperatively, all patients reported improvements in symptoms and QOL. The most prevalent preoperative symptom, heartburn, improved by 2.9 points. Of the four patients who remained with heartburn, all classified their operation as 3 (highly satisfactory) or 4 (extremely satisfactory). There were corresponding decreases in the frequencies of the other symptoms as shown in Figure 1. The 4.3% frequencies of

Example of Questionnaire

Nissen Fundoplication Data Sheet

Patient Details:

Patient Name _____ Patient Number _____
 Age ____ Sex ____ Race ____ Contact Number _____
 Date of Operation _____ Location of Operation _____

Operative Information	
Length of operation (hours)	
Post-operative stay (days)	
Time since operation (months)	
Intra-operative complications	

Preoperative Data	
Endoscopy	
pH monitoring	
Manometry	
Barium swallow	
Medications	

Preoperative Symptoms	
Duration of symptoms	
Heartburn	
Waterbrash	
Odynophagia	
Dysphagia (solids/liquids/saliva)	
Nocturnal asthma	
Weight loss	
Vomiting/nausea	
Regurgitation	
Abdominal pain	
Other symptoms	

dysphagia, nocturnal asthma and regurgitation correspond to one patient in each case. The symptom total score rose from a mean of 13.2 (theoretical maximum of 20) to 19.4; an increase of 6.2 points. This translates to a relative percentage

Social and emotional functions before-and-after surgery

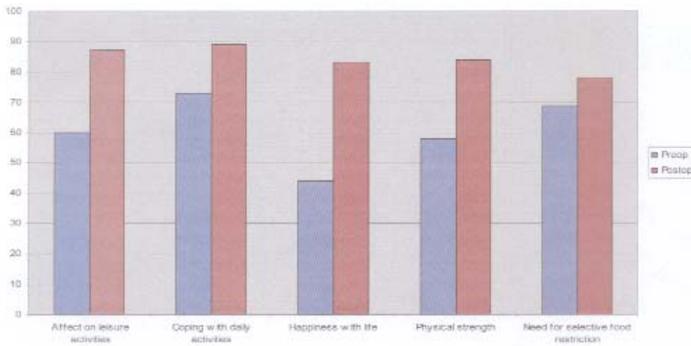


Fig. 2: Postoperative improvement in social and emotional functioning as broken down by individual concepts.

and emotional function scores averaged 13.2, out of a theoretical maximum of 20. The QOL total score, a combination of symptom score and emotional/functional score, had a theoretical maximum of 40, as it contained 8 domains. Its mean score was 26.4 preoperatively.

Statistical software package used for the analysis was Statistical Package for the Social Sciences (SPSS version 9.0). The data collected in this study were not normally

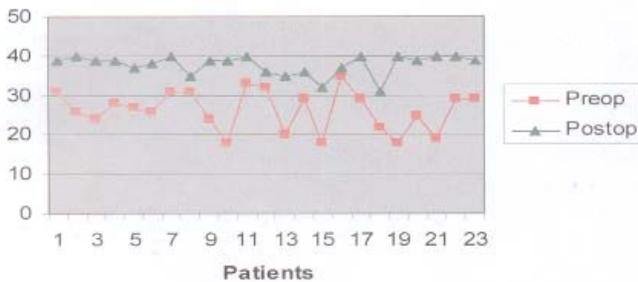


Fig. 3: Quality of life totals for individual patients pre- and post-operatively.

distributed and therefore were analyzed using non-parametric methods. The chosen test was the Wilcoxon signed-rank test (Wilcoxon matched-pairs test) which was used to analyze matched data and was found to be appropriate. Differences were considered to be significantly different from 0 (ie no change in score) if two-tailed p values were equal to or less

Postoperative symptoms	
Duration of symptoms Heartburn Waterbrash Odynophagia Dysphagia (solids/liquids/saliva) Nocturnal asthma Weight loss Vomiting/nausea Regurgitation Abdominal pain Other symptoms	

Preoperative social information	
Absence from work/month (days) Undertaking leisure activities (0-4) Coping with daily activities (0-4) Happiness with life (0-4) Physical strength (0-4) Selective food restriction/Diet (0-4)	

Postoperative data/social information	
Morbidity/Mortality Duration till return to work (days) Absence from work/month (days) Patient satisfaction (0-4) Undertaking leisure activities (0-4) Coping with daily activities (0-4) Happiness with life (0-4) Physical strength (0-4) Selective food restriction/Diet (0-4) Other issues/problems Medications	

increase of 47% or a percentage point increase of 31%. Only 4 patients (17.3%) remained on anti-reflux medications but the frequency of use was greatly reduced.

Heartburn and regurgitation were the two commonest symptoms preoperatively; nocturnal asthma was the fourth commonest. All three showed an identical 2.9 point increase postoperatively ($p < 0.001$), implying that the procedure was very successful in addressing these different symptoms equally (Fig. 1). Vomiting and nausea, the third most common preoperative complaints, improved by a slightly lower margin. Of the four patients (17.3%) who remained with heartburn postoperatively, three reported that it was of less severity. For the other, it was a new symptom which occurred approximately 2–3 times per month and was controlled with a reduced dosage of anti-reflux medications. There were a total of four patients that remained on anti-reflux medications; the other three continued the medication in spite of being asymptomatic for their own peace-of-mind. The individual indices that comprised social and emotional functioning each showed improvement, as seen in (Fig. 2) ($p < 0.001$). The mean score of overall social/emotional function increased from 13.2 to 18.3. This is a relative percentage increase of 38.6% and a percentage point increase of

25.5%. Nineteen patients (82.6%) had an improved social/emotional functioning postoperatively; 2 patients (8.6%) had the same functioning and 2 (8.6%) had lower functioning.

The combined scores or QOL totals increased from a mean score of 26.4 to 37.7. The individual increases are tabulated in Figure 3 ($p < 0.001$). This mean improvement of 11.3 points corresponds to a relative percentage increase of 42.8% or a percentage point increase of 28.3%. Fig. 2 illustrates the relative improvements among the individual indices. It shows a cumulative point increase for each aspect of social and emotional functioning. The QOL total was considered to be the most accurate representation of overall QOL; a device which is again similar to others that are more widely used. By combining the effects of both symptoms and social/emotional functioning, a more holistic representation of each patient’s life before-and after surgery could be garnered.

All patients reported improvement in QOL total. This is considered against the fact that there were four patients who had postoperative social/emotional functioning scores lower than or equal to their preoperative score. Since all patients showed an improvement in their symptom scores, it was compensated for and allowed for the universal increase in the QOL totals. Overall patient satisfaction had a mean value of 3.6, with 91% rating their operations as either three or four.

Percentage mortality was calculated as 4.2%. There were two patients who reported notable side-effects as a result of the operation. Gas bloat syndrome was experienced by one patient who still rated the operation as four. Dumping syndrome was experienced by the other who rated the operation as three. As stated earlier, all data were found to be statistically significant.

DISCUSSION

In terms of the procedure itself, the mean operating time (108 minutes) and mean postoperative hospital stay (1.2 days) were actually lower than in those of some previously published studies [130 minutes and 5 days respectively as described by Benassai *et al*] (11–13). However, the mortality rate of the present study was found to be higher than in many others due to the unfortunate outcome in one patient. The differences found in statistical comparison should perhaps be placed within the context of sample sizes. With this being a relatively small study, individual variations and outcomes assume greater statistical significance. In addition, the disparity in postoperative hospital stay averages could be partly attributed to the individual policies of the institutions at which the patients were housed.

The postoperative data collected is also in keeping with similar studies previously published (1–7). For example, Balci *et al* described that over 90% of patients experienced improvement of typical symptoms following laparoscopic Nissen fundoplication. QOL as measured by SF 36 and GERD-HRQL was also significantly improved (3). The im-

provement in the main complaints postoperatively is made more relevant on closer inspection. With these symptoms having been already established as the typical presentations of GERD, the favourable outcomes following the Nissen procedure is testament to its early effectiveness. It should be noted that all patients involved in the study satisfied the guidelines outlined by The Society of Gastrointestinal and Endoscopic Surgeons (SAGES), in that they remained symptomatic following medical management, and all but one of them had had preoperative endoscopy (14). Extended follow-up of these patients would be required to assess the long-term efficacy of the procedure (2).

The frequency of postoperative complications is approximately 8%, with the most common complication being early wrap herniation (10). Dysphagia represents an interesting entity within this study. It is recognized as both a potential symptom of moderate-to-severe GERD, as well as being a common complication of Nissen fundoplication. Balci *et al* described that 76% of patients who have undergone the Nissen procedure reported dysphagia within the first month postoperatively (early dysphagia). This number was found to decrease by the sixth postoperative month to 3.3% (3). It is interesting to note therefore, that within this study only 1 patient (4.3%) suffered from dysphagia after the operation. This figure for early dysphagia is much lower than what may have been projected based on previous data. It is also qualified by the fact that the sole patient who complained of dysphagia had suffered from it before surgery and experienced some improvement postoperatively.

Of the other potential postoperative side-effects, only gas bloat syndrome and dumping syndrome were encountered, a combined frequency of 8.7%. Both are considered to be early complications that improve with time.

Improvement of social and emotional functioning is a well-described and widely accepted outcome of the surgery (4–6). The data collected from this study reflects this. Although the questionnaire used measured only five specific parameters, it contained information that was similar to that found in other more widely used surveys. These include the Short Form 36 (SF-36) and the Gastroesophageal Reflux Disease-Health-Related Quality of Life form [GERD-HRQL] (3, 4). Thus, the data collected in this area was considered to be valid.

Patients were asked to quantify (on our 0 to 4 scale) their overall satisfaction with the procedure and its effects. The mean of 3.6 fell between being “highly” to “extremely satisfactory”. Overall, 22 patients (95.7%) rated their experience as satisfactory or above, compared with the study described by Bonnet *et al* in which 80% of patients reported being satisfied (4). With the use of specialized question-

naires and devices to analyze the details of the outcomes of the procedure, the patient’s summary perception of the process should also be accounted for. Ultimately, most people would not appreciate statistical figures and percentages more than they would appreciate actually feeling better and especially feeling that they were treated with both skill and compassion.

In conclusion, we found that GERD can be treated, with good results, by laparoscopic Nissen fundoplication when medical treatment fails. The procedure can be performed effectively and safely locally.

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