

A Clinical Audit of Post-Operative Outcomes of Laparoscopic Nissen's Fundoplication in a Single Center in Sub-Saharan Africa

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Summary

Introduction: Gastroesophageal reflux disease (GERD) is a common benign condition with a population prevalence of 18–28%. Laparoscopic antireflux surgery is increasingly being offered to patients with GERD in our setting; however, the outcomes remain unknown. **Methodology:** A retrospective clinical audit of patients who underwent laparoscopic Nissen's fundoplication in a single center. Data were summarized as mean (\pm SD) and median (interquartile range [IQR]); associations were analyzed with Chi square or Fischer's exact test. A Modified Visick scoring system was used to assess the severity of symptoms after surgery. Regression models were used to analyze the factors associated with recurrence. Kaplan–Meier plots were plotted, and cox regression models, hazard ratio, and their confidence intervals were calculated. **Results:** A total of 127 patients were identified, with 6 having had previous laparoscopic Nissen's fundoplication. Post-operative modified Visick scores at 2 weeks and 3 months were

1.04 (\pm 0.05) and 1.03 (\pm 0.04), respectively, for both typical and atypical symptoms. The recurrence rate was 12.6%, with 87.4% 5-year recurrence-free survival. **Conclusion:** Laparoscopic Nissen's fundoplication provides good control of both typical and atypical GERD symptoms with a low recurrence rate and a 5-year recurrence-free survival that is comparable to universal rates.

Keywords: GERD, Antireflux surgery, Laparoscopic Nissen's fundoplication

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Introduction

Gastroesophageal reflux disease (GERD) is the most common benign disorder affecting the esophagus with a global prevalence ranging from 18% to 28% (1). It involves the pathological spontaneous and involuntary reflux of gastric contents into the esophagus as a consequence of reduced lower esophageal sphincter (LES) pressures compared with gastric pressure causing troublesome symptoms or complications (2).

GERD may present with typical symptoms (heartburn, regurgitation, and dysphagia) or with atypical symptoms such as chronic cough, asthma, laryngitis, or dental erosions. GERD may also present with serious complications such as erosive esophagitis, esophageal stricturing, and Barrett's esophagus, all which impact negatively on the patient's quality of life. The recurrent inflammation of the lower esophagus due to chronic

exposure to gastric refluxate eventually leads to dysplasia and malignant transformation (1).

The diagnosis of GERD may be made based on the presence of typical symptoms, response to empirical treatment with proton pump inhibitors (PPIs), or by evidence of reflux on esophageal-gastro-duodenoscopy (OGD), LES manometry, impedance testing, and 24-h pH monitoring (3). The first-line management of GERD involves lifestyle modification and use of acid lowering medication. Typically, up to 80% of patients will have symptom resolution within 8 weeks of PPI therapy; however, GERD is a chronic long-standing disease, and a number of patients continue to have troublesome symptoms. The medical management of GERD is long term and individual based with unclear endpoints, with a majority of patients in need of continuous, intermittent, or on-demand PPI therapy (4).

Laparoscopic Nissen's fundoplication (LNF) is currently the gold standard antireflux procedure, and the only known cure for reflux disease, and is recommended in patients with severe reflux esophagitis, symptomatic hiatal hernia, and intolerance to long-term PPI therapy (5). However, this procedure has been associated with a 17% recurrence rate and a variable technique-dependent complication rate of up to 18%. A number of factors including technical factors, patient factors, and patient selection have been found to be responsible for this outcome (6).

LNF is increasingly being offered to patients with GERD in our local setting; however, there is scanty data on the patient selection and outcomes. The aim of this clinical audit was to evaluate the indications, patient selection, and outcomes of LNF, a major outcome being recurrence, in a single center.

Methodology

Study design

This is a retrospective clinical audit whereby patients who had undergone LNF were identified from patient records of patients managed from January 2018 to April 2023. The data were collected in May 2023.

Study population

The study population was inclusive of all patients who had undergone LNF in a single facility by a single surgeon from January 2018 to April 2023. The recommended patient selection for LNF is as per the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) guidelines; this includes patients with Los Angeles grade C/D reflux esophagitis, symptomatic patients with hiatal hernia (Hill's Grade C/D), and patients with typical reflux symptoms who have minimal improvement with medical therapy or are dissatisfied with long-term PPI use (5). Patients with atypical symptoms eligible for LNF are those with evidence of reflux on esophageal manometry, 24-h ambulatory pH monitoring, and imaging (barium swallow, CT, and MRI chest), having excluded other causes through extensive investigations.

Patients generally excluded from an LNF include those patients with multiple laparotomies/open abdominal surgeries and patients with comorbid conditions that are incompatible with laparoscopy.

Definition of recurrence

Recurrence after antireflux surgery has been defined as heartburn, regurgitation, and/or vomiting >1/week; use of anti-secretory drugs because of GERD symptoms >1/week, jejunal or parenteral feeding because of GERD; macroscopic esophagitis or new-onset Barrett's esophagus; reflux-index >4; GER demonstrated on upper gastrointestinal (UGI) contrast study; wrap herniation found on UGI contrast study or by endoscopy; or redo fundoplication (7).

Description of procedure

The procedure begins with a sharp division of the gastrohepatic ligament (Kuster's window) with sparing of the hepatic branch of the vagus nerve. The left phreno-esophageal ligament, gastrophrenic ligament, and gastrosplenic ligament are divided with cautery. The short gastric arteries are not routinely divided (8, 9). Dissection on the right side proceeds with division of the right phreno-esophageal ligament. Mediastinal dissection is carried on proximally until visualization of the inferior pulmonary vein—this allows for adequate

mobilization of the esophagus to bring the LES at least 3–5 cm below the diaphragm (5, 10–12). The retro-esophageal window is bluntly created with precaution to ensure preservation of the posterior vagus nerve. A crural repair is carried out by apposing both pillars of the crura with simple interrupted sutures using 2.0 ethibond suture. A 1.5–2 cm 360° posterior wrap is fashioned at the LES and secured with three sutures, with the middle suture anchored at the gastroesophageal junction (13). The wrap is then pexyed (anterior gastropexy) to the right crus with a simple suture using ethi-bond 2.0 suture (11).

The post-operative dietary regimen involves nil per oral for 24 h, followed by 24 h of clear liquid diet and graduation to blended feeds thereafter. The patient is discharged after 72 h on analgesics.

Data collection

The data were collected using a data collection sheet. Information collected included age, gender, body mass index (BMI), comorbid conditions, duration and type of reflux symptoms (typical and atypical); duration of use and satisfaction/outcome of medical therapy for reflux control; investigations for reflux and their findings; outcome of surgery, PPI use after surgery; and surgical complications and quality of life assessment. Post-operative resolution of symptoms was determined using the modified Visick scoring system for GERD as shown in Table 1 (14).

Table 1. Modified Visick score for gastroesophageal reflux disease

Grade 1	Excellent outcome, no symptoms.
Grade 2	Very good, mild symptoms, patient considers results perfect.
Grade 3	Good, mild or moderate symptoms, not controlled with care but not interfering with work or enjoyment of life.
Grade 4	Satisfactory, moderate symptoms not controlled with care, but only occasionally interfering with life; patient and doctor consider results satisfactory.
Grade 5	Unsatisfactory: moderate or severe symptoms, compromising work or enjoyment of life. Patient and doctor dissatisfied.

Data analysis

Continuous data were presented as mean (standard deviation) if normally distributed and median (interquartile range [IQR]) if nonparametric. Assessment of normal distribution of continuous data was done using both graphical and statistical methods: The Kolmogorov–Smirnov test. To assess association on categorical data, Chi square or Fischer's exact test was used appropriately and expressed as χ^2 (1, n). Univariate and multivariate regression models were used to analyze the factors associated with recurrence. Kaplan–Meier plots were used to assess survival for different subclasses in the group, with cox regression models and hazard ratio and their confidence intervals.

Ethical considerations

All data were anonymized and accessed only by authorized personnel. Ethical approval was sought from the KNH/UoN Ethics Committee, ethical approval reference KNH/ERC/01/PUB/05.

Results

Patient characteristics

A total of 127 patients were identified from hospital records. Table 2 gives a summary of the patient characteristics. Six of the patients had a previous history of LNF with symptoms suggestive of recurrence.

Presentation

Out of 127 patients, only 25% (32) presented with a triad of typical symptoms (heartburn, regurgitation, and epigastric pain); 74% of the patients presented with heartburn, 70% with regurgitation, and 56% with epigastric pain. The most common atypical presentation of GERD was an acidic taste in the mouth (47%) followed by throat pain (45%), non-cardiac chest pain (28%), hoarseness (28%), chronic cough (20%), globus sensation (19%), and dysphagia (17%) (Table 2, column 3).

The median duration of medical treatment for GERD was 24 months (IQR 12–52 months); with 98% reporting minimal to no improvement on medical therapy.

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Table 2. A summary of patient charac

		Yes n (%)	Total N (%)	Test	p value
	111 (87.4%)	16 (12.6%)			
Age in years^a (mean)	43 ± 15.1	42.7 ± 14.9	43 ± SD 15	0.2	0.84
BMI^b (median)	27.5	28.0	28 ^c	0.06	0.81
Gender (M:F) = 1:3					
Male	28 (87.5%)	4 (12.5%)	32	0.19	0.89
Female	84 (88.4%)	11 (11.5%)	95		
Comorbid conditions					
Hypertension	6 (86%)	1 (14%)	7 (5.5%)	0.121	0.94
Diabetes mellitus	3 (75%)	1 (25%)	4 (3.1%)	0.751	0.68
Asthma	19 (86%)	3 (14%)	22 (17%)	0.134	0.94
Osteoarthritis	3 (100%)	0 (0%)	3 (2.4%)	0.516	0.77
Typical symptoms					
Heartburn	84 (89%)	10 (11%)	94 (74%)	0.09	0.76
Regurgitation	81 (91%)	8 (9%)	89 (70%)	3.58	0.06
Epigastric pain	49 (88%)	7 (12%)	56 (44%)	0.05	0.82
Dysphagia	14 (82%)	3 (18%)	17 (13%)	0.65	0.42
Atypical symptoms					
Globus sensation	21 (88%)	3 (12%)	24 (19%)	0.004	0.95
Throat pain	49 (86%)	8 (14%)	57 (45%)	0.49	0.78
Hoarseness	25 (89%)	3 (11%)	28 (22%)	0.15	0.93
Chronic cough	20 (80%)	5 (20%)	25 (20%)	2.5	0.28
Excess sputum production	1 (100%)	0 (0%)	1 (<1%)	0.23	0.89
Recurrent rhinitis	1 (100%)	0 (0%)	1 (<1%)	0.23	0.89
Non-cardiac chest pain	31 (86%)	5 (14%)	36 (28%)	0.23	0.89
Headache	2 (50%)	2 (50%)	4 (3%)	5.7	0.055
Acidic taste	51 (86%)	8 (14%)	59 (47%)	0.32	0.85
Others	79 (87%)	12 (13%)	91 (71%)	0.7	0.7
Duration of symptoms and medical treatment (months)			Median 24 months (IQR 12–52)		
Response to medical treatment					
No improvement	13 (81%)	6 (19%)	16 (13%)	4.4	0.21
Mild improvement	68 (88%)	9 (12%)	77 (61%)		
Moderate improvement	1 (50%)	1 (50%)	2 (1.5%)		
Symptom-free	0 (0%)	0 (0%)	0 (0%)		
Missing data	30 (94%)	2 (6%)	32 (25%)		
Hiatal hernia					
Hill's A	19(95%)	1 (5%)	20 (16%)	0.10	0.23
Hill's B	5(83%)	1(17%)	6 (4.7%)		
Hill's C	27(90%)	3(10%)	30 (24%)		
Hill's D	50(88%)	7(12%)	57 (45%)		
Missing data	11 (79%)	3 (21%)	14 (11%)		
Reflux esophagitis					
None	61(88%)	8(12%)	69 (54.3%)	1.23	0.94
LA-A	10 (91%)	1 (9%)	11 (8.7%)		
LA-B	9 (90%)	1(10%)	10 (7.9%)		
LA-C	16 (84%)	3 (16%)	19 (15%)		
LA-D	5 (100%)	0 (0%)	5 (3.9%)		
Missing data	11 (85%)	2 (15%)	13 (10.2%)		

^aKolmogorov–Smirnov (K-S) test for age (no recurrence: 0.084, *p* 0.97) and (with recurrence: 0.101, *p* 0.2) hence normally distributed. Student *t*-test used to assess the two means.

^bK-S test for BMI (no recurrence: 0.11, *p* 0.007) and (with recurrence: 0.201, *p* 0.12). Independent sample median test used to assess difference in the two medians.

^cGrand median.

Table 3. Visick scores at 2 weeks at 3 months post laparoscopic Nissen’s fundoplication

Symptoms	Visick scores at 2 weeks post laparoscopic Nissen’s fundoplication							Visick scores at 3 months post Laparoscopic Nissen’s fundoplication							Paired t-test	p value			
	Vs 1 n (%)	Vs 2 n (%)	Vs 3 n (%)	Vs 4 n (%)	Vs 5 n (%)	Mean	σ	Vs 1 n (%)	Vs 2 n (%)	Vs 3 n (%)	Vs 4 n (%)	Vs 5 n (%)	Mean	σ					
Heart burn	122 (96.1)	5 (3.9)	0 (0)	0 (0)	0 (0)	1.04	0.195	122 (96.1)	5 (3.9)	0 (0)	0 (0)	0 (0)	1.04	0.195	0.000	1.00			
Regurgitation	120 (94.5)	7 (5.5)	0 (0)	0 (0)	0 (0)	1.06	0.229	125 (98.4)	2 (1.6)	0 (0)	0 (0)	0 (0)	1.02	0.125	1.679	0.096			
Dysphagia	104 (81.9)	23 (18.1)	0 (0)	0 (0)	0 (0)	1.18	0.387	116 (91.3)	10 (7.9)	1 (0.8)	0 (0)	0 (0)	1.09	0.325	2.069	0.041			
Epigastric pain	115 (90.6)	12 (9.4)	0 (0)	0 (0)	0 (0)	1.09	0.294	111 (87.4)	16 (12.6)	0 (0)	0 (0)	0 (0)	1.13	0.333	-0.852	0.396			
Globus sensation	123 (96.9)	4 (3.1)	0 (0)	0 (0)	0 (0)	1.03	0.175	122 (96.9)	5 (3.1)	0 (0)	0 (0)	0 (0)	1.04	0.195	-0.377	0.707			
Throat pain	115 (90.6)	12 (9.4)	0 (0)	0 (0)	0 (0)	1.09	0.294	123 (96.9)	4 (3.4)	0 (0)	0 (0)	0 (0)	1.03	0.375	2.169	0.032			
Hoarseness	126 (99.2)	1 (0.8)	0 (0)	0 (0)	0 (0)	1.01	0.089	124 (97.6)	3 (2.4)	0 (0)	0 (0)	0 (0)	1.02	0.152	-1.000	0.319			
Chronic Cough	124 (97.6)	3 (2.4)	0 (0)	0 (0)	0 (0)	1.02	0.152	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	1.746	0.083			
Excess sputum production	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	—	—			
Asthma	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	—	—			
Recurrent rhinitis	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	—	—			
Non cardiac chest pain	121 (95.3)	6 (4.7)	0 (0)	0 (0)	0 (0)	1.05	0.213	124 (97.6)	3 (2.4)	0 (0)	0 (0)	0 (0)	1.02	0.152	1.346	0.181			
Headache	127 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1.00	0.000	124 (97.6)	3 (2.4)	0 (0)	0 (0)	0 (0)	1.02	0.152	-1.746	0.083			
Average mean (13.56/13)							1.04	0.05	Average mean (13.41/13)							1.03	0.04		

On OGD, 77% had a hiatal hernia (Hill’s Grade C and D) with 21% having severe reflux esophagitis (Los Angeles grade C/D).

The mean modified Visick score at 2 weeks and 3 months post-operatively was 1.04 (SD 0.05) and 1.03

(0.04), respectively (Table 3). Twenty-four (19%) of the patients were maintained on PPI therapy 2 weeks after surgery, and out of these only 7 (5.5%) continued PPI use up to 3 months. A total of 16 (12.5%) patients were, however, on PPI at 3 months for symptom control.

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Post-operative complications

Common early complications (24 h to 7 days post-surgery) were dysphagia (20%), hiccups (7%), and surgical site infection (4%). The prevalence of hiccups remained constant through to the end of the study at 7%. New-onset dysphagia and bloating was identified in 35% and 31% of the patients respectively. The prevalence of late complications (1–3 months after surgery) was dysphagia 41% (52/127); 49 cases which had mild dysphagia while three patients had moderate dysphagia; difficulty in belching 10% (13/127) with 13 mild cases and 4 moderate cases; bloating at 38% (48/127) with 36 mild cases and 12 moderate cases; and

flatulence 14% (18/127) with 10 mild and 8 moderate cases, respectively.

Recurrence

A total of 16 patients (12.6%) met the criteria for recurrence after surgery. There was no association between recurrence and gender (χ^2 , 0.19 $p = 0.88$); BMI (Pearson's $R = 0.28$, $p = 0.789$) (Table 2). The median time to recurrence for recurrences was 9 months, with a range of 4–32 months. There was no difference in survival between male and female patients (Log rank 0.03, $p = 0.85$) (Figure 1).

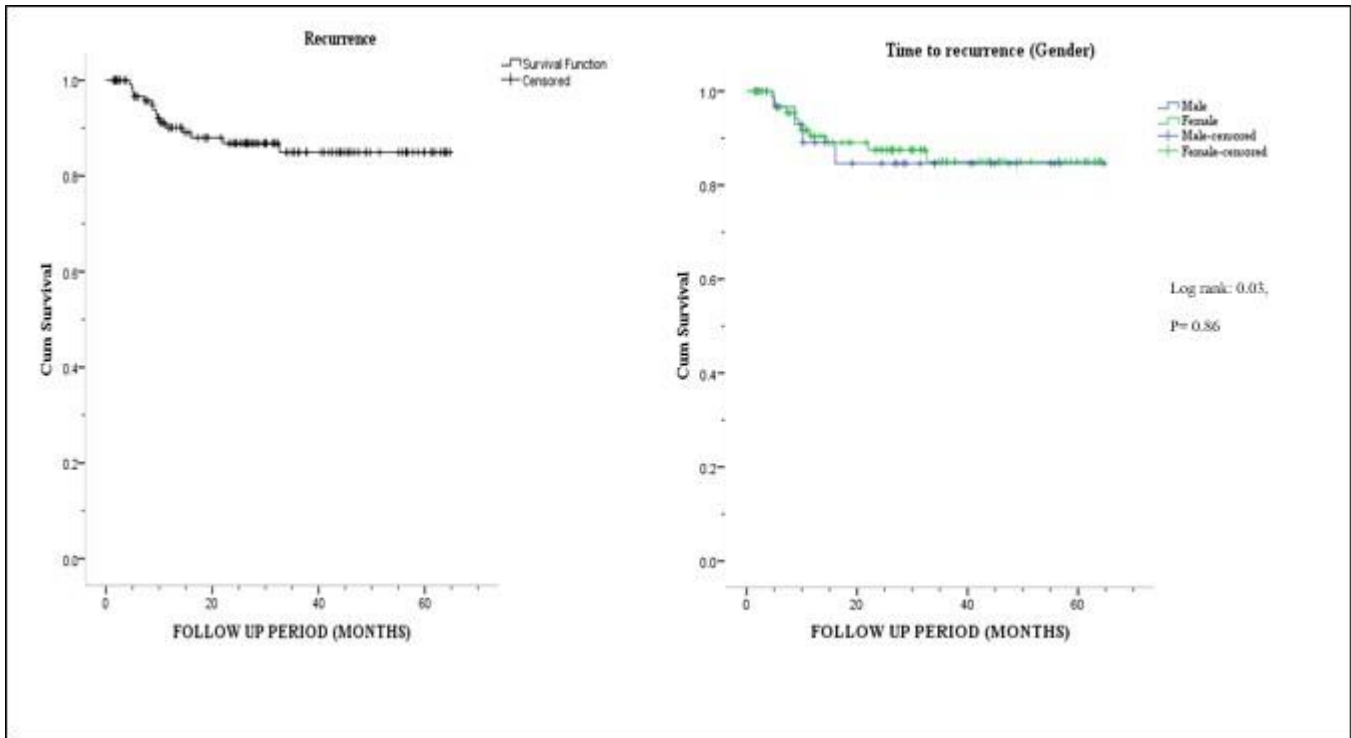


Figure 1. Kaplan–Meier curve for overall time to recurrence and time to recurrence based on gender.

Table 4. Cox regression model

	B coefficient	p value	HR	95.0% CI for Exp (B)	
				Lower	Upper
Age	-0.010	0.757	0.990	0.932	1.053
BMI	0.252	0.114	1.287	0.941	1.760
Weight (kg)	-0.124	0.082	0.883	0.768	1.016
Diabetes mellitus	-3.465	0.043	0.031	0.001	0.890
Heartburn	-6.176	0.001	0.002	0.000	0.086
Chronic cough	-3.810	0.067	0.022	0.000	1.304

The cox regression model did not identify significant risk factors to recurrence; however, the analysis suggests that patient with diabetes mellitus (HR = 0.03; CI = 0.001, 0.890; $p = 0.043$) and heartburn (HR = 0.002; CI = 0.000, 0.086; $p = 0.001$) have a lower risk of recurrence (Table 4). However, this is to be interpreted with caution because the number of patients with diabetes mellitus was too small (Table 1).

Discussion

The objective of this audit was to assess the post-operative outcome of patients managed with LNF for GERD. The patient population is predominantly female with normal to obese BMI. This is consistent with the global presentation where women are more likely to report symptoms of GERD, with the prevalence of symptoms directly related to increase in body weight (3).

In this study, we note that LNF provides adequate control of both the typical and atypical symptoms of GERD both in the short and long terms in patients with a poor response to PPI therapy. The LOTUS trial demonstrated the superiority of LNF to long-term PPI therapy in controlling both heartburn and regurgitation (15). Studies investigating the benefit of antireflux surgery on patients with atypical symptoms have also demonstrated benefit in select patients where causality with reflux has been established (16). A study by Ugliono et al., which recruited 73 patients with refractory GERD to antireflux surgery, reported a satisfaction rate of 86.3% and statistically significant reduction in both typical and atypical symptoms with statistically significant improvement in quality of life (17).

An interesting finding is the long duration of medical treatment in patients with predominantly no to minimal improvement on medical therapy. This may reflect a resistance to acceptance of laparoscopic Nissen's fundoplication as an option in the management of GERD, or a lack of knowledge among physicians leading to late patient referrals as reflected by scanty to non-existent literature on LNF in sub-Saharan Africa (6).

Despite the technical advances in LNF, the procedure still carries a recurrence rate that ranges from 3% to 30% (6, 18), which is comparable to this study's findings. Recurrences are related to surgical/technical and patient-related factors. Patient-related factors that have consistently been found to predict recurrence in studies include female gender, advancing age (>61 years), large hiatal hernia >3cm, and the presence of comorbid condition (19, 20). These findings are not consistent with this study and this may be attributed to the number of patients, and type of patients included in the study, who are not representative of the general population.

Study limitations

This is a retrospective clinical audit from a single center with surgeries done by a single surgeon in a private practice setting, hence a likelihood for selection bias, making this study not generalizable to the general population. The sample size is also small, with use of medical records with notable key missing information.

Conclusion

LNF provides good control of both typical and atypical GERD symptoms with a low recurrence rate and a 5-year recurrence-free survival that is comparable to universal rates. This study could form a basis for prospective studies to evaluate the outcomes of this intervention.

Author contributions

All authors contributed equally to Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Software, Validation, Visualization and writing, reviewing & editing of the original draft.

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