

# Early Laparoscopic Nissen Fundoplication for Recurrent Reflux Esophagitis: A Cost-Effective Alternative to Omeprazole

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## ABSTRACT

**Background:** Eighty percent of patients treated medically for gastroesophageal reflux disease relapse after treatment. Many of these patients require indefinite treatment with omeprazole to prevent recurrence. Nissen fundoplication has been shown to be effective, safe and cost effective in the management of gastroesophageal reflux disease. We suggest a treatment algorithm, which encourages early surgical intervention in cases of recurrent esophagitis after a previously successful two-month course of omeprazole.

**Methods:** We have offered laparoscopic Nissen fundoplication since 1993. Patients who received Nissen fundoplication since 1990 were asked to report return to baseline activity, medications, and lifestyle changes. Concurrent chart review of patients treated with omeprazole was conducted to analyze cost.

**Results:** Patients receiving laparoscopic Nissen fundoplication were discharged significantly sooner and spent significantly less time convalescing when compared to those who underwent open Nissen fundoplication. Laparoscopic Nissen fundoplication became cost effective at 1.5 to 2 years when compared to omeprazole.

**Conclusion:** Based on cost analysis, patient satisfaction, acceptable complication rate, and efficient use of time and resources, we recommend laparoscopic Nissen fundoplication as the appropriate treatment in patients who develop recurrent esophagitis after a two-month treatment with omeprazole.

**Key Words:** Laparoscopy, Nissen fundoplication, Reflux esophagitis, Omeprazole.

## INTRODUCTION

Medical management of gastroesophageal reflux disease (GERD) with H-2 blockers, antacids, and omeprazole is effective, but as many as 80% of patients managed medically relapse when omeprazole is stopped. Further, medical management is expensive, and many patients are now placed on lifetime maintenance doses of omeprazole to prevent the complications of reflux. Nissen fundoplication is an effective treatment for GERD, and multiple studies comparing open Nissen fundoplication (ONF) to laparoscopic Nissen fundoplication (LNF) show equivalent short-term control of symptoms. No studies in the literature combine cost analysis with patient satisfaction and outcome. We questioned whether LNF was cost effective compared to current medical management. We conducted a retrospective chart review and survey of hospital stay, convalescence, control of symptoms, and length of medical management concurrent with a cost analysis of medical management, ONF, and LNF for the treatment of GERD. We then developed a treatment algorithm, which emphasizes early surgical management in patients who relapse after an initial successful two-month treatment with omeprazole.

## MATERIALS AND METHODS

Laparoscopic Nissen fundoplication has been performed at William Beaumont Army Medical Center since 1993. The charts of all patients who underwent laparoscopic and open Nissen fundoplication since 1990 were reviewed through 1995. Patients were asked to report medications required before and after surgery, time to return to baseline activity, and if they would recommend the procedure to others. Patients under 18 years of age were excluded. Thirty-five patients underwent a Nissen fundoplication during the study interval. Sixteen patients who received LNF and nine who received ONF were available for interview.

Concurrent review of 46 charts was undertaken of patients with GERD managed with omeprazole. The only data recorded was amount and duration of medication directed at controlling GERD symptoms. Cost analysis data was collected through the Procurement Offices

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of Pharmacy and Surgery as well as the Department of Treasury and Third Party Collections. An assumption was made that initial work-up and follow-up costs for both medical and surgical patients were equal. The cost of medical management includes follow-up esophagogastroduodenoscopy, office visits, and emergency department visits for non-cardiac chest pain.<sup>1</sup> Statistical analysis was performed using student's t-test. P values <0.05 were considered significant.

**RESULTS**

Average hospital stay was 7.38 days in the open group and 2.70 days in the laparoscopic group (P<0.05) (Figure 1). The convalescence time, calculated as time from surgery until return to work, was 35.3 days in the open group and 17.90 days in the laparoscopic group (P<0.05) (Figure 2). All patients in both groups would recommend the procedure to others. Patients in both groups averaged 24.9 months of H-2 blocker treatment and 10.75 weeks of omeprazole treatment. The annual cost of 40 mg of daily omeprazole at government rate is \$1,500.71. The annual cost of 20 mg of daily omeprazole with 10 mg of cisapride three times daily is \$1,154.67. Cost of LNF is 2,276.58 based on 1995 reimbursement rates. One patient in the LNF group experienced return of symptoms at six weeks, which resolved with subsequent ONF. One patient in the LNF group experienced gas bloat syn-

drome, which was improving, but not resolved, at one year. One patient in the LNF group required occasional cimetidine postoperatively. One patient in the open group acquired postoperative pneumonia, which resolved with treatment. No patients reported lifestyle modifications postoperatively, and there were no deaths. Cost effectiveness was achieved at two years in patients treated with 40 mg of omeprazole daily.

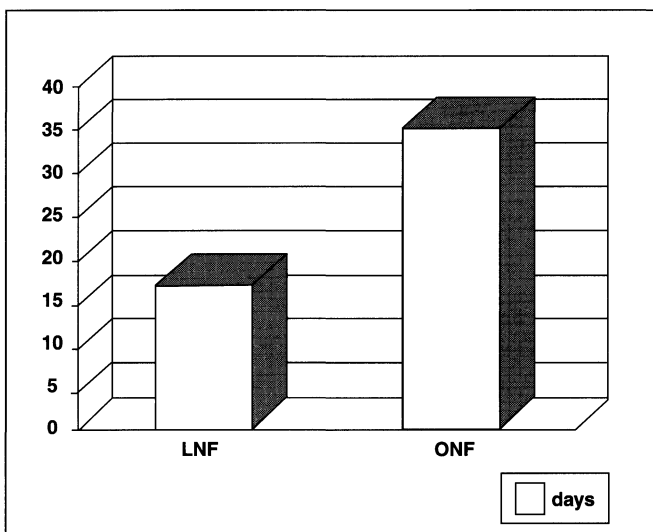


Figure 2. Mean number of days from surgery until return to work in the LNF (17.9) and ONF (35.3) P<0.05.

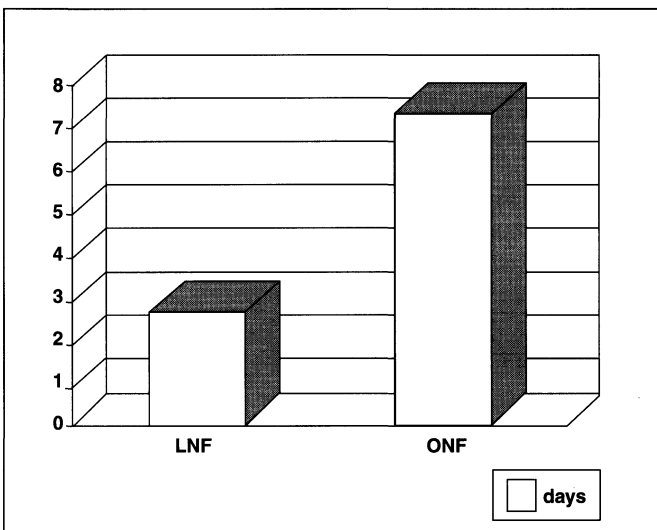


Figure 1. Mean hospital days after LNF (2.70) and ONF (7.38) P<0.05.

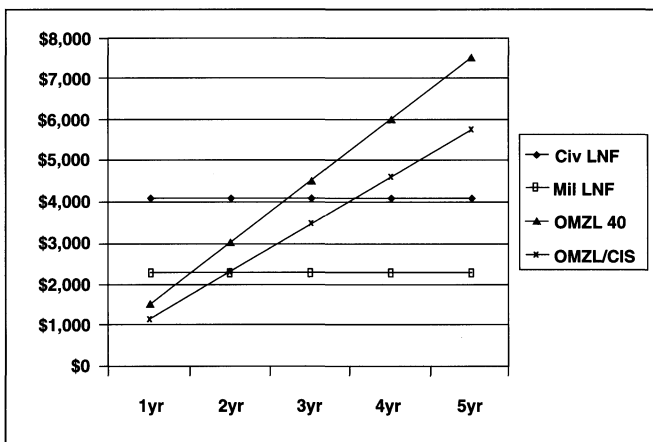


Figure 3. Cost of civilian and military LNF compared to medical therapy with 40 mg omeprazole and 20 mg omeprazole with 10 mg cisapride three times a day over a 5 year period.

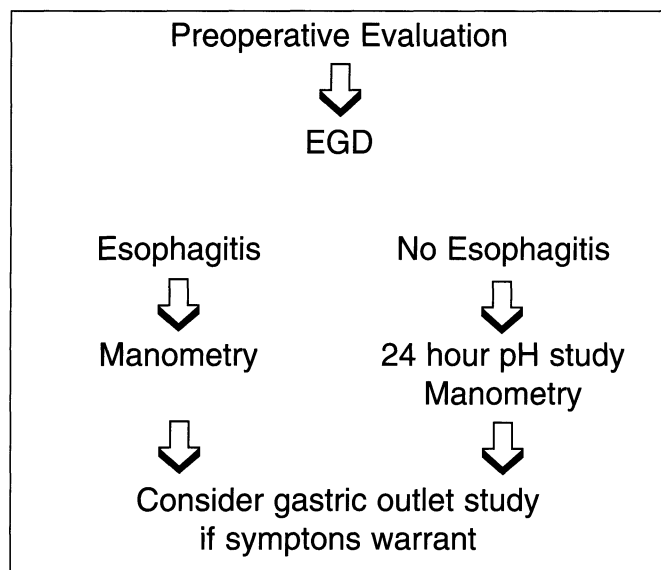


Figure 4. Recommended preoperative work-up prior to LNF.

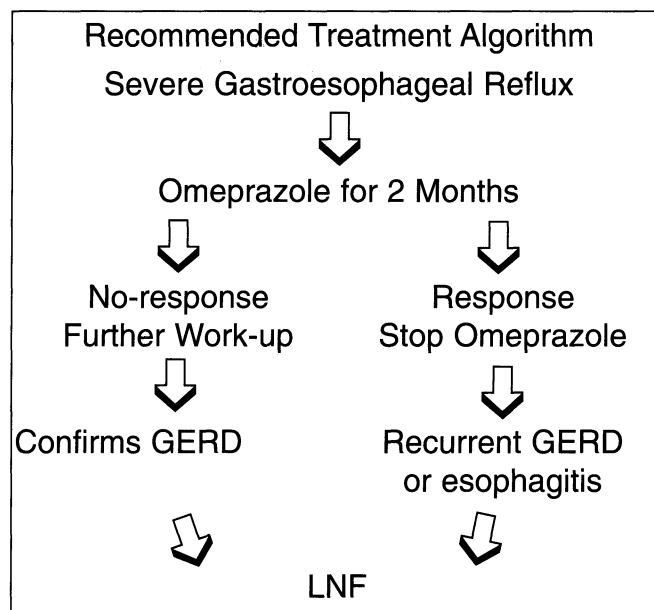


Figure 5. Recommended treatment algorithm for surgical treatment of GERD.

## DISCUSSION

A large prospective randomized study has shown that ONF is superior to medical management with H-2 receptor antagonists in healing esophagitis.<sup>2</sup> Unfortunately, this study predated wide-spread use of omeprazole in this country, and, to date, no prospective randomized trial has compared proton pump antagonists to surgery for control of esophagitis. Several studies have shown that an appropriate maintenance therapy for prevention of recurrent esophagitis is 10–20 mg omeprazole every-day.<sup>3,4</sup> This regimen requires a compliant patient, frequent follow-up, and substantial cost. Multiple studies have shown omeprazole in doses of 20–40 mg daily results in complete resolution of esophagitis within 60 days;<sup>5-7</sup> however, cessation of omeprazole results in recurrent esophagitis in 80% of patients.<sup>5</sup> Patients who do not resolve their esophagitis or symptoms on 20–40 mg daily of omeprazole in 60 days warrant evaluation for other non-GERD causes for their symptoms. The literature is clear that medical therapy will resolve most if not all symptoms from GERD. However, this approach requires indefinite medical therapy. Expense with this approach includes follow-up visits for prescription refill, the medication itself and emergency department and car-

diac care unit visits for atypical chest pain. Despite having these issues clearly defined in the literature, a 1995 *New England Journal of Medicine* article and editorial stated that preferred management for GERD was long-term (>4 years) omeprazole and cisapride.<sup>8,9</sup> Further, the long-term implications of omeprazole treatment remain unclear. No gastric cancer has occurred in humans attributable to omeprazole to date, but the implications of hypergastrinemia, corpus gastritis, argyrophil cell hyperplasia, and atrophic gastritis remain unclear.<sup>10,11</sup> In our institution, treatment with surgery became cost effective at 1.5 years in patients treated with 20 mg of omeprazole daily and 10 mg cisapride three times daily. Cost effectiveness was achieved at two years in patients treated with 40 mg omeprazole daily (Figure 3). No significant long-term complications were observed in the surgical groups, and complications were not noted in the medical group.

## CONCLUSION

Despite small numbers in our study, we feel that laparoscopic Nissen fundoplication is the logical treatment for GERD in patients who fail a 2-month trial of omeprazole treatment and meet criteria for fundoplication (Figure

4). We suggest, based on patient satisfaction, cost analysis, acceptable complication rate, and efficient use of time and resources, that laparoscopic Nissen fundoplication is the appropriate treatment in patients who develop recurrent esophagitis after two months of treatment with omeprazole (**Figure 5**).

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