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CHAPTER 11

Feasibility of a laparoscopic Nissen fundoplication as a day-case procedure

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Abstract

Background

The aim of this prospective double-cohort pilot study is to evaluate the feasibility and desirability of laparoscopic Nissen fundoplication (LNF) performed in day-care when compared to laparoscopic cholecystectomy (LC) in day-care.

Methods

Patients who underwent a LNF in day-care were prospectively evaluated. LNF patients were treated according to LC in day-care protocol. Outcome parameters were EQ-5D, Visual Analogue Scale (VAS) and patient satisfaction.

Results

From October 2005 to March 2008, 22 patients underwent LNF and 48 patients LC in day-care. After LNF, 21 out of 22 (95%) patients were discharged the same day. Seven (32%) patients were seen postoperatively on the Emergency Department with dysphagia or pain and two (9%) patients were readmitted. After LC, 45 out of 48 (94%) patients were discharged the same day. Six (12.5%) patients were seen postoperatively on the Emergency Department because of wound infection or pain and three (6%) were readmitted. EQ-5D and VAS scores were significantly worse after LNF in day-care, repeated measurements $P < 0.0001$ and $P < 0.0001$. In a telephone survey 66.7% preferred a short hospital stay over day-care surgery after LNF compared to 30.9% after LC ($P = 0.011$).

Conclusions

LNF in day-care is feasible and safe, but postoperative pain scores are high and most prefer short hospital stay.

Introduction

The incidence of gastro esophageal reflux disease (GERD) has increased in the Western world for the last 50 years.¹ A 360° Nissen fundoplication is the most common surgical treatment for this disease nowadays², and the first laparoscopically performed Nissen fundoplication was performed in 1991.³ Randomized controlled trials have shown that the success rate of surgery is similar for the open and laparoscopic approach. Advantages for a laparoscopic procedure were less morbidity, a shorter hospital stay and a better cosmetic result.⁴ Nowadays, the preferred treatment for GERD is a laparoscopic Nissen fundoplication (LNF).

As surgical and anesthetic techniques get better, day-care surgery is gaining popularity. Laparoscopic cholecystectomy (LC), for example, is performed routinely in day-care surgery in many centers. Several randomized studies⁵ have demonstrated that there is no difference in morbidity, number of readmissions and quality of life between inpatient or outpatient procedure. Advantages of a day-care procedure are lower costs and, in some countries, shorter waiting lists. In 1995 Milford et al.⁶ performed the first LNF as a day-care procedure. This article has been included in the only systematic review published⁷, which concluded that LNF in day-care was feasible and safe.

Very few papers have been published describing the results of LNF in day-care and only one of those studies is a double cohort study.⁸

Therefore, the aim of this prospective double-cohort pilot study was to evaluate the feasibility and desirability of LNF in day-care with respect to postoperative pain, quality of life and patient satisfaction when compared to LC in day-care.

Materials and Methods

Patients undergoing LNF or LC in day-care from September 2005 to March 2008 were included in this prospective double-cohort pilot study. Clinical indications for LNF were: symptoms of GERD confirmed by gastroscopy, manometry, and 24-hours pH-metry. Symptomatic cholelithiasis proven by abdominal ultrasound was an indication for LC. The surgeon and anesthesiologists decided if a patient was suitable for day-care surgery. Inclusion criteria for day-care surgery were: American Society of Anesthesiologists (ASA) grade I, II or stable III⁹, Body Mass Index (BMI) below 40 kg/m², living no more than 1.5 h away from the hos-

pital, the company of a responsible adult for a minimum of 24 h after the operation, being under medical attention of a general practitioner, and telephonic accessibility. Presence of a large hiatus hernia or a prior abdominal operation was not an exclusion criteria.

At the day of surgery patients had to be present at 7.30 a.m. Intervention started at 8.00 or 10.00 a.m. for the first and second case, respectively. As premedication 1g acetaminophen and 50 mg tramadol was administered. Benzodiazepines were not part of the standard premedication and were only administered if the patient was anxious, as evaluated by the attending anesthesiologist. General anesthesia was induced and maintained by target-controlled infusion of 2.5-3 µgram propofol plus remifentanyl. To facilitate endotracheal intubation mivacurium or rocuronium was used. Patients were mechanically ventilated with oxygen air.

Prophylactic medication for postoperative nausea and vomiting (PONV) was administered peroperatively using the following medication scheme: at the start of the operation 10 mg dexamethason, and at the end 15 µgram/kg dehydrobenzperidol plus 4 mg ondansetron. Forty-five minutes before closing 0.15 mg/kg morphine was given as postoperative pain medication. Nasogastric tubes were used to decompress the stomach during operation and removed before extubation. Urinary catheters were not utilized.

Surgical technique

For a LNF, three 10-mm and two 5-mm trocars were inserted in the umbilicus and upper abdomen. For LC, two 10-mm and two 5-mm were used. At the end of the operation the port sites were infiltrated with a long-acting local anesthetic (bupivacaine). All LNF were performed or supervised by a senior surgeon (W.A.B.). At the recovery room, postoperative pain management consisted of 150 mg acetaminophen intravenously and, if required, for PONV, 2 mg ondansetron, 15 µgram/kg dehydrobenzperidol, and/or metoclopramide intravenously.

Patients were permitted to drink and eat shortly after discharge from the Post Anesthesia Care Unit (PACU) and were scheduled to leave the day-care center before 7.30 p.m. Discharge criteria according to Post Anaesthesia Discharge Score System¹⁰ were: <20% deviation of blood pressure and pulse compared with preoperative values, balanced gait without dizziness, pain acceptable and pain regulated with oral analgesics, no excessive nausea or vomiting, and minimal blood loss. Before discharge patients were seen both by the surgeon as well as the anesthesiologist. Postoperative pain medication differed between the first group of 10 LNF patients (group I) and the last group of 10 LNF patients (group II). Group I received 1 g acetaminophen and 50 mg tramadol, both 4 times a day. Group II and all LC received the same analgesics plus 50 mg diclofenac and 40 mg esomeprazol three times a day. Pain medication was reduced as agreed with each patient. Information about alarm symptoms plus relevant telephone numbers was given to the patient and their companion. Patients were called the next day by a nurse of the day-care center. Two months after surgery patients were seen for outcome assessment by the responsible surgeon.

Primary endpoints were: health related quality of life, postoperative pain and patient satisfaction. Health related quality of life was assessed by EQ-5D, which is a simple, self-administered questionnaire in which a patient scores 1, 2, or 3, reflecting no problems, moderate

problems and extreme problems, respectively, scored on five dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. These scores were used to generate a tariff reflecting the preference value associated with a given health state. The utility by Dolan et al.¹¹ was used to calculate the overall health status (i.e., the EQ-5D tariff), in which a tariff of -0.6 represented the worst quality of life and 1.0 best quality of life. Postoperative pain was assessed by the Visual Analogue Scale (VAS), where 0 means no pain and 10 worst pain. Both had to be filled out at postoperative day 1 until 7, and at day 14. To assess patient satisfaction, patients with a successful discharge were contacted by telephone and asked for their preference for either day-care or short hospital stay. Secondary endpoints were percentage of successful discharges before 7.30 p.m. at the day of surgery, number of unplanned visits to the Emergency Department, readmission rate, and morbidity within 30 days.

Results for this pilot study for continuous data were expressed as median and range. Analyses of EQ-5D tariff and VAS were only done on the responding patients by linear mixed repeated-measure models. Other data were compared by Mann Whitney U and Chi-square tests. In all analyses, $P < 0.05$ was considered as statistically significant.

Results

Between September 2005 and March 2008, 22 consecutive patients underwent a LNF for GERD as a day-case procedure. All these patients were included in this study. Of the 22 LNF patients, 20 completed and returned the EQ-5D questionnaire and VAS (response rate 91%). A group of 48 patients underwent a LC as a day-case procedure, of whom 83% ($n=40$) responded. The 10 non-responding patients are shown in Table 1.

	Laparoscopic cholecystectomy	Laparoscopic Nissen fundoplication
Included, n	48	22
Responders, % (n)	83% (40)	91% (20)
Non-responders, % (n)		
- Postoperative complication	2% (1)	4.5% (1)
- No postoperative complication	15% (7)	4.5% (1)

Except for the sex distribution, there were no significant differences in baseline characteristics between the groups (Table 2). None of the operations were converted to an open procedure in either group. In the LNF group, all but one (95%) were discharged before 7.30 p.m. at the day of surgery. One patient had to stay for an overnight observation, because of the development of subcutaneous emphysema in the face and neck preoperatively. This patient was discharged the next day without any complications. Successful discharge was achieved in 94% ($n=45$)

after LC. Two patients had to stay for observation because of perioperative complication managed nonoperatively and one because of excessive pain. In the LNF group 32% (n=7) of the patients visited the Emergency Department; one with bladder retention and six with dysphagia or pain, of whom two (9%) patients were readmitted. One patient required a laparoscopic drainage of a parahiatal abscess and one patient had infection of the umbilical port site. These postoperative complications resulted in hospital stay of 17 and 7 days, respectively. Of the patients in the LC group, 12.5% (n=6) visited the Emergency Department because of pain. Readmission occurred in 6% (n=3); one patient had acute pancreatitis, one a wound infection of the umbilical port site and one was admitted for adequate pain management. This resulted in hospital stay of 5, 3, and 3 days, respectively. The complication rate after LNF and LC was 14% (n=3; bladder retention, parahiatal abscess, wound infection) and 4% (n=2; pancreatitis, wound infection), respectively. None of these differences were significant.

Table 2 Demographics of patients undergoing LC or LNF

	Laparoscopic cholecystectomy	Laparoscopic Nissen fundoplication	P
N	48	22	
Male : female	9 : 39	14 : 8	<0.001 [†]
Age	46 (17-64)	47 (19-66)	0.51 [†]
ASA I : II : III	31 : 17 : 0	10 : 11 : 1	0.11 [‡]
BMI (kg/m ²)	26.1 (18-43)	27.6 (21-36)	0.44 [†]
Surgery time	87 (39-186)	84 (49-149)	0.51 [†]

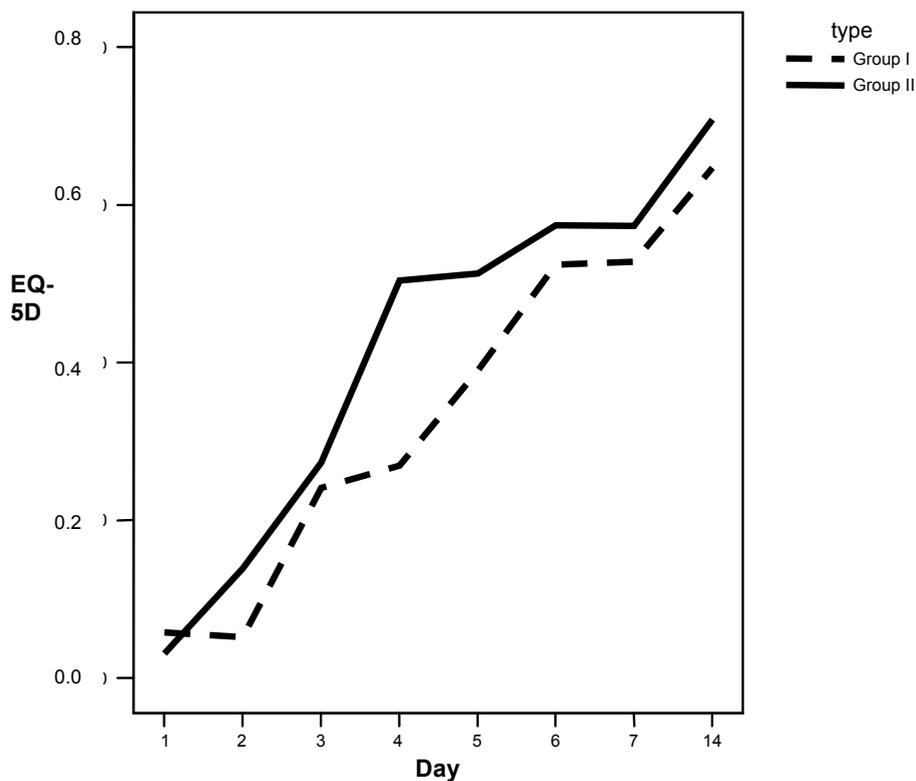
Data: median (range) / [†]Mann Whitney U test / [‡]Kruskal-Wallis test / LC = laparoscopic cholecystectomy / LNF = laparoscopic Nissen fundoplication / ASA = American Society of Anaesthesiologists / BMI = Body Mass Index

Interim analysis was performed after the first group of ten LNF patients (group I). In this group postoperative EQ-5D tariff and VAS were high at all postoperative days. After the interim analysis 50 mg diclofenac three times daily and 40 mg esomeprazol once daily was added to the postoperative pain medication (group II). Visual judgement of group I compared to group II did not show a different relation between time point and EQ-5D tariff or VAS score (Figure 1). Therefore, LNF subgroups were combined for further analysis, but an interaction term (treatment group x dose) was included as a covariate in the estimation of the average score difference over time between LNF and LC. Figures 2 and 3 show the EQ-5D tariff and VAS scores of all LNF patients and LC patients. On all postoperative days on both scales patients in the LNF group scored significantly worse (Figures 2 and 3). Repeated measures (mixed model) analysis indicated that the average increase per day in EQ-5D tariff was 0.033 points for both treatment groups. Corrected for the interaction between dose and treatment group, the average difference between the groups was 0.024 tariff points (Figure 2;

$P < 0.0001$); without correction, the difference was the same. On the VAS patients scored on average -0.161 per day lower. Corrected average difference between the two interventions was 2.41 points on the VAS in advantage of the LC group (Figure 3; $P < 0.0001$); without correction, this difference was 2.93 VAS points.

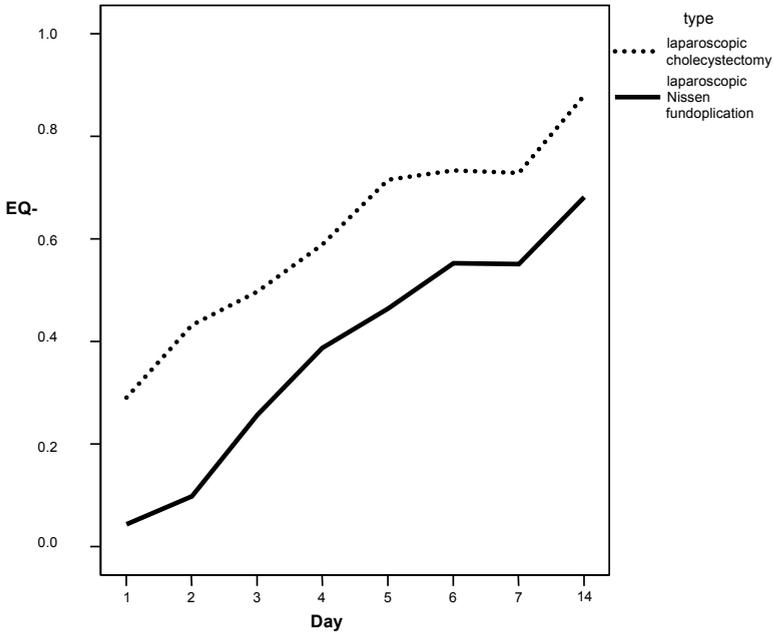
When asked for their preference in case of the hypothetical situation of having the same procedure again, 14 out of 21 (66.7%) LNF patients preferred a short hospital stay. In the LC group this was 13 out of 42 (30.9%) patients. This difference was statistically significant ($P = 0.011$).

Figure 1 Postoperative EQ-5D tariff of first 10 LNF versus last 10 LNF



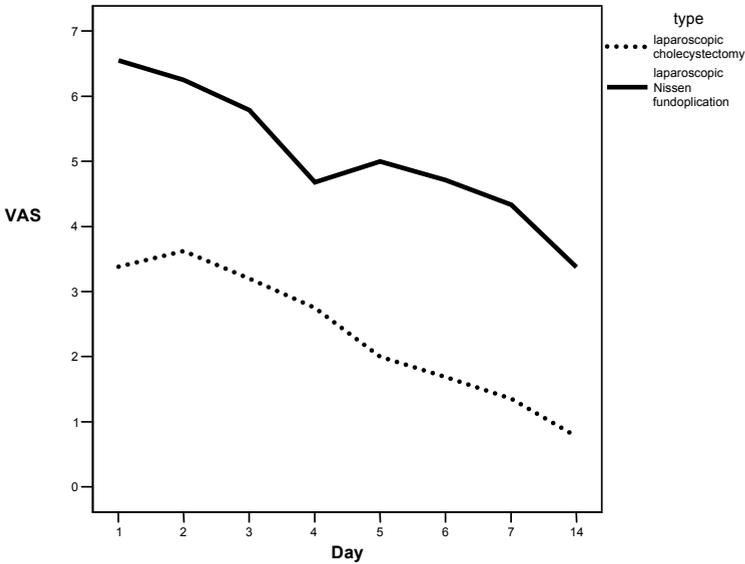
LNF = laparoscopic Nissen fundoplication / Group I = first 10 LNF patients / Group II = last 10 LNF patients

Figure 2 Postoperative EQ-5D tariff of LC versus LNF



P < 0.0001, regression coefficient 0.033; linear mixed model
 LC = laparoscopic cholecystectomy / LNF = laparoscopic Nissen fundoplication

Figure 3 Postoperative VAS of LC versus LNF



P < 0.0001, regression coefficient -0.161, linear mixed model
 VAS = Visual Analogue Scale / LC = laparoscopic cholecystectomy / LNF = laparoscopic Nissen fundoplication

Discussion

This study evaluated the feasibility and desirability of LNF in day-care surgery. The results were compared with a prospective cohort of day-care LC. Although LNF in day-care was successful in terms of discharge rate and morbidity, postoperative pain scores were higher despite adequate pain medication. Quality of life and patient satisfaction were much lower when compared with LC. In general in day-care, VAS for pain at home should not exceed 4. In the present study pain scores after LNF exceeded 4, and therefore LNF in day-care might not be desirable.

There are several conditions that an operation in day-care surgery has to meet in order to obtain acceptance by physicians: no increased morbidity or mortality compared with inpatient procedure, high success rate of same-day discharge, and satisfied patients.

Only one systematic review^{6;12-14} has been published about LNF in day-care. However, only four^{6;12-14} out of the seven studies were truly day-care surgery, as three studies^{8;15;16} defined discharge within 24 h after surgery as day-care surgery, when an overnight hospital admission is actually a short hospital stay. Of a total of 61 patients, questioned in two studies^{8;14, 45} (73%) would undergo the same procedure in day-care again. This review concluded that LNF in day-care was feasible and safe, but a judgment about patient satisfaction and preference could not be made.

Six studies^{6;12-14;17;18} have been published about LNF in true day-care. In these studies morbidity and readmissions ranged from 0% to 11% and discharge rates from 82.5% to 100%. Our results were comparable with these data from literature.

Preference to undergo the same procedure in day-care again was only 33.3% in the present study. This is very low compared to other studies^{12;14;17;18}, which report preference for day-care surgery of 63.4-95%. In one study¹⁷ patients were asked to complete an 11-point numeric rating scale for pain and nausea within 5 days postoperatively, ranging from 0 (no pain/ no nausea) to 10 (worst pain/uncontrollable vomiting). The reported pain scores in that study were similar to those reported in the study by Keulemans et al.¹⁹, who studied LC in day-care. A possible explanation for the difference in pain between this present study and the study of Marriete et al.¹⁷ was the infiltration of the diaphragm with bupivacaine (long-acting local anesthetic) before closure apart from the routine infiltration of the port-site wounds. The highest patient satisfaction (95%) was achieved in the study of Bailey et al.¹² In this study however, patients were asked for their preference at the evening of discharge, which might be not the optimal moment to evaluate this question.

The only other double-cohort study is done by Narain et al.⁸ It is of great importance to perform a double-cohort study when comparing postoperative pain. Postoperative pain after a laparoscopic procedure is thought to be caused by the port-site wounds.²⁰ LC is performed with four trocars. For LNF, only one more 10-mm trocar is needed. The expectation of this study that postoperative pain after LNF would be comparable to that after LC, as there is only one additional port-site, proved to be incorrect. This difference might be caused by the intra-abdominal dissection in front of the aorta freeing the distal thoracic esophagus in LNF.

Another possible explanation for the difference in pain between LNF and LC could be the duration of operation and anesthesia, assuming more postoperative pain when surgery takes longer.²¹ In this study, however, median duration of surgery was actually 3 minutes shorter in the LNF group.

After the interim analysis pain medication had to be adjusted as VAS exceeded 4 and quality of life was low. The aim of this study was to compare LNF to LC in day-care. Nevertheless, postoperative pain medication was different for the first group of ten LNF patients. The reason for this was the restraining attitude of the anesthesiologists to prescribe nonsteroidal anti-inflammatory drugs (NSAIDs) to patients with GERD and, as Trondsen et al.¹⁴ had shown excellent patient results and satisfaction with minimal pain medication (acetinophen and codeine), alternative medication was not given. This difference in pain medication for the first ten LNF patients could have been a bias. However, corrected analysis taking the difference in pain medication into account did not relevantly alter the results.

Recently new interventions to treat GERD have been developed. One of the new surgical antireflux devices is a magnetic sphincter²², positioned around the distal esophagus laparoscopically. It might be of interest to study postoperative pain in these patients, since periesophageal dissection is minimal and therefore postoperative pain might be less in these patients.

In conclusion, LNF in day-care is feasible and safe but, once at home, patients have high pain scores and quality of life is diminished in comparison with LC. Since more than two-thirds of the patients preferred a short hospital admittance, conventional LNF can best be performed in a short-stay setting. In order to justify LNF in day-care further research is needed to adjust postoperative analgesia.²³

References

- 1) Dent J, El-Serag HB, Wallander MA, Johansson S. Epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut* 2005; 54(5):710-717.
- 2) Rossetti M, Hell K. Fundoplication for the treatment of gastroesophageal reflux in hiatal hernia. *World J Surg* 1977; 1(4):439-443.
- 3) Dallemagne B, Weerts JM, Jehaes C, Markiewicz S, Lombard R. Laparoscopic Nissen fundoplication: preliminary report. *Surg Laparosc Endosc* 1991; 1(3):138-143.
- 4) Ackroyd R, Watson DI, Majeed AW, Troy G, Treacy PJ, Stoddard CJ. Randomized clinical trial of laparoscopic versus open fundoplication for gastro-oesophageal reflux disease. *Br J Surg* 2004; 91(8):975-982.
- 5) Gurusamy K, Junnarkar S, Farouk M, Davidson BR. Meta-analysis of randomized controlled trials on the safety and effectiveness of day-case laparoscopic cholecystectomy. *Br J Surg* 2008; 95(2):161-168.
- 6) Milford MA, Paluch TA. Ambulatory laparoscopic fundoplication. *Surg Endosc* 1997; 11(12):1150-1152.
- 7) Ng R, Mullin EJ, Maddern GJ. Systematic review of day-case laparoscopic Nissen fundoplication. *ANZ J Surg* 2005; 75(3):160-164.
- 8) Narain PK, Moss JM, DeMaria EJ. Feasibility of 23-hour hospitalization after laparoscopic fundoplication. *J Laparoendosc Adv Surg Tech A* 2000; 10(1):5-11.
- 9) Ansell GL, Montgomery JE. Outcome of ASA III patients undergoing day case surgery. *Br J Anaesth* 2004; 92(1):71-74.
- 10) Chung F. Recovery pattern and home-readiness after ambulatory surgery. *Anesth Analg* 1995; 80(5):896-902.
- 11) Dolan P, Roberts J. Modelling valuations for Eq-5d health states: an alternative model using differences in valuations. *Med Care* 2002; 40(5):442-446.
- 12) Bailey ME, Garrett WV, Nisar A, Boyle NH, Slater GH. Day-case laparoscopic Nissen fundoplication. *Br J Surg* 2003; 90(5):560-562.
- 13) Ray S. Result of 310 consecutive patients undergoing laparoscopic Nissen fundoplication as hospital outpatients or at a free-standing surgery center. *Surg Endosc* 2003; 17(3):378-380.
- 14) Trondsen E, Mjaland O, Raeder J, Buanes T. Day-case laparoscopic fundoplication for gastro-oesophageal reflux disease. *Br J Surg* 2000; 87(12):1708-1711.
- 15) Cohn JC, Klingler PJ, Hinder RA. Laparoscopic Nissen fundoplication as an ambulatory surgery center procedure. *Today's Surg Nurse* 1997; 19(4):27-30.
- 16) Finley CR, McKernan JB. Laparoscopic antireflux surgery at an outpatient surgery center. *Surg Endosc* 2001; 15(8):823-826.
- 17) Mariette C, Piessen G, Balon JM, Guidat A, Lebuffe G, Triboulet JP. The safety of the same-day discharge for selected patients after laparoscopic fundoplication: a prospective cohort study. *Am J Surg* 2007; 194(3):279-282.
- 18) Victorzon M, Tolonen P, Vuorialho T. Laparoscopic floppy Nissen fundoplication for gastro-oesophageal reflux disease is feasible as a day-case procedure. *Scand J Surg* 2006; 95(3):162-165.
- 19) Keulemans Y, Eshuis J, de HH, de Wit LT, Gouma DJ. Laparoscopic cholecystectomy: day-care versus clinical observation. *Ann Surg* 1998; 228(6):734-740.
- 20) Bisgaard T, Klarskov B, Rosenberg J, Kehlet H. Characteristics and prediction of early pain after laparoscopic cholecystectomy. *Pain* 2001; 90(3):261-269.

- 21) Aubrun F, Valade N, Coriat P, Riou B. Predictive factors of severe postoperative pain in the post-anesthesia care unit. *Anesth Analg* 2008; 106(5):1535-41, table.
- 22) Ganz RA, Gostout CJ, Grudem J, Swanson W, Berg T, DeMeester TR. Use of a magnetic sphincter for the treatment of GERD: a feasibility study. *Gastrointest Endosc* 2008; 67(2):287-294.
- 23) Prospect. www.postoppain.org . 2008. Ref Type: Internet Communication