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Population-based trend analysis of laparoscopic Nissen and Toupet fundoplications for gastroesophageal reflux disease

U. Zingg · L. Rosella · U. Guller

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Abstract
Background The Nissen and Toupet fundoplications are the most commonly used techniques for surgical treatment of gastroesophageal reflux disease. To date, no population-based trend analysis has been reported examining the choice of procedure and short-term outcomes. This study was designed to analyze trends in the use of Nissen versus Toupet fundoplications, and corresponding short-term outcomes during a 10-year period between 1995 and 2004.
Methods A trend analysis was performed of 873 patients (Toupet: 254 patients, Nissen: 619 patients) prospectively enrolled in the database of the Swiss Association for Laparoscopic and Thoracoscopic Surgery.
Results The frequency of the performed techniques remained stable during the observation period (p value for trend 0.206). The average postoperative and total length of hospital stay both significantly decreased during the 10-year period from 5.6 to 4.0 days and 6.8 to 4.8 days, respectively (both p values for trend <0.001). The average duration of surgery decreased significantly from 141 minutes to 121 minutes (p value for trend <0.001). There was a trend towards less complications in later years (2000–2004) compared to early years (1995–1999, $p = 0.058$). Conversion rates were significantly lower in later years compared with early years ($p = 0.004$).
Conclusions This is the first trend analysis in the literature reporting clinical outcomes of 873 prospectively enrolled patients undergoing Nissen and Toupet fundoplications during a 10-year period. The proportion of laparoscopic Nissen versus Toupet fundoplications remained stable over time, indicating that literature reports of the advantages of one procedure over the other had minimal influence on surgeons' choice of technique.
Length of hospital stay, duration of surgery, morbidity, and conversion rate decreased over time, reflecting the learning curve. Clearly, patient outcomes have much improved during the 10-year observation period.

Keywords Laparoscopic fundoplication · Nissen · Toupet · Trend analysis · Outcome

Since its introduction in 1991, laparoscopic fundoplication has become the standard surgical treatment for gastroesophageal reflux disease (GERD) [1]. Compared with open surgery, the minimally invasive approach is associated with reduced morbidity, shorter length of hospital stay, and decreased postoperative pain [2, 3]. Long-term reflux control and subjective well being after laparoscopic reflux surgery are excellent [4, 5].

Various wrap types and positions have been described in the literature, ranging from 90 degrees to 360 degrees and positioning posterior or anterior to the esophagus [6]. The most frequently used techniques are the Nissen 360 degree

U. Zingg
Department of Surgery, University Hospital Basel, 4031 Basel, Switzerland
e-mail: uzingg@gmail.com

L. Rosella
Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

U. Guller (✉)
Division of Visceral Surgery and Transplantation, Department of Surgery, Inselspital, University of Bern, 3010 Bern, Switzerland
e-mail: Ulrich.guller@gmail.com

fundoplication and the Toupet 270 degree fundoplication with a posterior wrap [7]. Whether either of these techniques is superior remains a matter of great debate. The Nissen procedure appears to be associated with superior reflux control compared with the Toupet procedure, but also is associated with a higher rate of postoperative dysphagia [8]. These findings led in the late 1990s to the development of a tailored concept, choosing a total or partial wrap depending on preexisting esophageal motility disorders [9]. In recent years, a number of randomized trials comparing Nissen with Toupet fundoplication have been published, with conflicting results [10–14]. Two trials [10, 11] failed to demonstrate an advantage for either technique. However, three trials [12–14] favored the Toupet procedure, in particular because of lower postoperative dysphagia rates. No study has shown a disadvantage of the partial wrap in terms of reflux control.

Despite no proven advantage of the Nissen fundoplication over the Toupet procedure, it is much more common in clinical practice, with rates between 60 and 87% compared with 13–40% for the latter [15–18]. A number of trend analyses have been performed during the last decade, concentrating on the frequency of open versus laparoscopic GERD surgery. These studies demonstrated an increased use of the laparoscopic technique [19–22]. However, no study has ever specifically analysed whether there has been a change in the use of the different procedures over time and whether outcomes improved with increasing experience.

Hence, the primary objective of the present investigation was to analyze the trend in use of Nissen versus Toupet fundoplications during a 10-year time period from 1995 to 2004 as well as a trend of short-term outcomes. A secondary objective was to compare short-term outcomes between Nissen and Toupet fundoplications.

Patients and methods

Since 1989, the Swiss Association for Laparoscopic and Thoracoscopic Surgery (SALTS) has been prospectively collecting data from patients undergoing various laparoscopic procedures. Approximately two thirds of all laparoscopic operations performed in Switzerland are entered into the database [23].

More than 130 parameters are recorded for each patient, including demographics, treatment details, intra- and postoperative morbidity, mortality, conversion rates, and hospital length of stay. Data are recorded on standardized forms by the responsible surgeon and transferred into the electronic database (Qualicare®; Qualidoc Ltd., Bern, Switzerland) by a data manager qualified to verify completeness and accuracy of the data.

Data collection

In the present study, all patients in the SALTS database undergoing laparoscopic Nissen and Toupet fundoplications for GERD performed between January 1995 and December 2004 were included. Morbidity was classified as intraoperative, i.e., all complications occurring during the surgery, such as bleeding or injury to adjacent organs, or postoperative. Postoperative morbidity was further divided into surgical, i.e., complications related directed to the surgery, such as hematoma, leakage, or surgical site infection, and general, i.e., complications not directly related to surgery, such as pulmonary or cardiac disorders.

Statistics

An experienced Ph.D. statistician with particular interest in population-based outcomes research performed all statistical computations (LR). Rates and average/median values of outcomes were tested for changes over time using chi-square (χ^2) tests for trend and generalized linear models for continuous outcomes. Both unadjusted and risk-adjusted analyses were performed. For the adjusted analyses, rates were modelled using a Poisson regression model, which included age, ASA, gender, and year to ascertain whether significant differences were observed over time after adjusting for the variables in the model.

For intraoperative complications, surgical postoperative complications, general postoperative complications, and conversion rates, the overall numbers of incidents per year were relatively small. Therefore, no statistical trend analysis was performed. Instead, the 10-year time period was divided into two 5-year time spans and the outcomes were compared between early years (1995–1999) and late years (2000–2004) using a Fisher's exact test or Wilcoxon rank-sum test as appropriate.

A significance level of $\alpha = 0.05$ was used for all tests. All p values were two-sided. All statistics were calculated using SAS statistical software V 9.1 (Cary, NC).

Results

Demographics and perioperative data

A total of 873 patients were analyzed. There were 572 (65.5%) men and 301 (34.5%) women with a mean age of 46.7 years (standard deviation [SD] 13.0). The average American Society of Anesthesiologists (ASA) score was 1.6 (SD 0.6, range: 1–3). Average postoperative length of stay was 4.6 days (SD 2.9), and average total length of stay 5.6 days (SD 3.3). Details of operative and postoperative data are shown in Table 1.

Table 1 Operative and postoperative details of all patients ($n = 873$)

Surgical technique	
Nissen (%)	619 (70.9)
Toupet (%)	254 (29.1)
Conversion (%)	13 (1.5)
Morbidity	
Intraoperative (%)	42 (4.8)
Postoperative surgical (%)	19 (2.2)
Postoperative general (%)	27 (3.1)
Reoperations (%)	9 (1)
30-day mortality (%)	0 (0)

Table 2 Overall number of fundoplications and the type of procedure performed during the 10-year time period between 1995 and 2004

	All fundoplications ($n = 873$) (%)	Nissen fundoplications ($n = 619$) (%)	Toupet fundoplications ($n = 254$) (%)
1995	83 (100)	59 (71)	24 (29)
1996	123 (100)	79 (64)	44 (36)
1997	99 (100)	72 (73)	27 (27)
1998	92 (100)	67 (73)	25 (27)
1999	73 (100)	47 (64)	26 (36)
2000	89 (100)	64 (72)	25 (28)
2001	131 (100)	92 (70)	39 (30)
2002	89 (100)	72 (81)	17 (19)
2003	59 (100)	43 (73)	16 (27)
2004	35 (100)	24 (69)	11 (31)

Trend analysis by year

The overall number of fundoplications and the type of procedure performed remained constant from 1995 until 2002 (Table 2). After 2002, a decline of procedures performed was observed. The frequency of the two techniques, Nissen and Toupet, remained stable during the observation period (p value for trend 0.206) as shown in Fig. 1. Between 64 and 81% of all procedures were Nissen fundoplications, whereas the Toupet technique accounted for 19–36%.

Postoperative length of hospital stay decreased significantly from an average of 5.6 days in 1995 to 4 days in 2004 (p value for trend <0.001). Similarly, total length of hospital stay decreased from an average of 6.8 to 4.8 days (p value for trend <0.001). Duration of operation decreased significantly over time, from an average of 141 min in 1995 to 121 min in 2004 (p value for trend <0.001).

There were significantly more conversions in the early years (1995–1999) compared with the later years (2000–2004, $p = 0.004$) (Table 3). Rates of complications were higher in the early years compared with the later years (50 complications vs. 28 complications, $p = 0.058$). No deaths in the 30-day postoperative period were reported over the 10-year period.

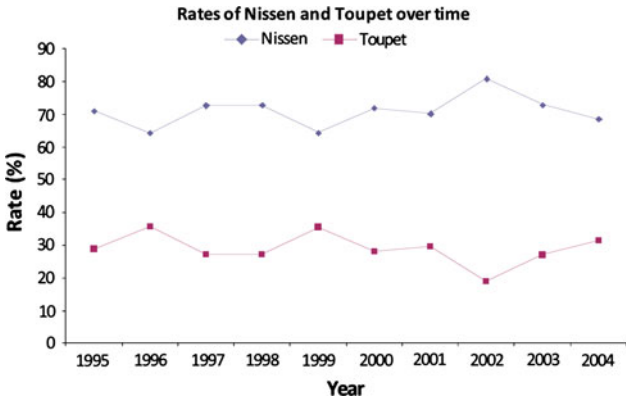

Fig. 1 Trend analysis of the use of Nissen versus Toupet fundoplications from 1995 to 2004

Toupet versus Nissen fundoplications

Age, gender, and ASA score were not significantly different between patients who underwent Nissen versus Toupet fundoplication. Furthermore, intraoperative or postoperative morbidity and conversion rates were similar between the two procedures (Table 4). Mean postoperative and total length of hospital stay were significantly shorter in the Toupet group ($p = 0.025$ and $p = 0.035$, respectively; Table 4).

Discussion

The present investigation is the first trend analysis in the literature reporting clinical outcomes of 873 prospectively collected patients who underwent Nissen or Toupet fundoplications during a 10-year period. This study demonstrates that the ratio of Nissen to Toupet fundoplications was constant between 1995 and 2004. Between two thirds and three quarters of the procedures performed were Nissen fundoplications. Furthermore, there was a trend toward significantly shorter length of hospital stay, shorter duration of surgery, less complications, and conversions during the 10-year time period, reflecting the learning curve. No differences with respect to short-term outcomes were found between patients who underwent Toupet or Nissen fundoplications, with the exception of a shorter length of hospital stay in the former group.

A number of randomized trials have addressed the question whether Nissen or Toupet fundoplication is superior, with conflicting results. Two trials did not show a

Table 3 Intra- and postoperative morbidity and conversion rates stratified according to time period

	1995–1999 ($N = 470$)	2000–2004 ($N = 403$)	p value
Nissen procedures (%)	324 (68.9)	295 (73.2)	0.179
Overall number of patients with complications (%)	50 (10.6)	28 (6.9)	0.058
Intraoperative complications (%)	28 (6.0)	14 (3.5)	0.112
Surgical postoperative complications (%)	11 (2.3)	8 (2.0)	0.818
General postoperative complications (%)	18 (3.8)	9 (2.2)	0.239
Conversions (%)	12 (2.6)	1 (0.3)	0.004

Table 4 Comparison of Nissen and Toupet fundoplications performed between 1995 and 2004

	Nissen ($n = 619$)	Toupet ($n = 254$)	p value
Mean age (SD)	46.5 (13.2)	47.3 (12.5)	0.369
Gender			
Male (%)	403 (65.1)	169 (66.5)	0.683
Female (%)	216 (34.9)	85 (33.5)	
Mean ASA score (SD)	1.6 (0.6)	1.6 (0.6)	0.269
Mean postoperative length of stay (SD)	4.7 (3.0)	4.3 (2.7)	0.025
Mean total length of stay (SD)	5.8 (3.3)	5.4 (3.2)	0.035
Conversion (%)	12 (1.5)	1 (0.4)	0.123
Intraoperative complications (%)	30 (4.8)	12 (4.7)	1.000
Surgical postoperative complications (%)	11 (1.8)	8 (3.1)	0.210
General postoperative complications (%)	18 (2.9)	9 (3.5)	0.668
Reoperations (%)	7 (1.1)	2 (0.8)	1.0

SD standard deviation

difference in terms of reflux control or mid-term or long-term postoperative dysphagia [10, 11]. However, one of the trials demonstrated a higher rate of immediate postoperative dysphagia after Toupet procedures [10]. In contrast, three randomized trials showed an advantage of the Toupet procedure in terms of reflux control and the occurrence of postoperative dysphagia [12–14]. Dysphagia after Nissen procedures is a frequent phenomenon; however, this usually disappears within a few months [13, 24, 25]. Whether the total wrap itself is responsible for the dysphagia remains a matter of debate. Dysphagia also has been attributed to other factors, such as size of the bougie used intraoperatively, the length of the wrap, and failure to divide the short gastric vessels, resulting in a not fully mobilized fundus [8, 25]. However, a recently published, randomized trial challenged this theory, showing no difference in outcome of Nissen fundoplications regardless of whether the short gastric vessels were divided [26]. Another possible cause for postoperative dysphagia may be scar tissue formation, resulting in narrowing of the hiatus [27]. Despite reports in the literature of advantages of a partial wrap, the proportion of Nissen and Toupet procedures performed remained unchanged over the years, which is one of the most important and somewhat surprising finding of this study. This may reflect the lack of convincing evidence regarding the superiority of either of the procedures. Rather than adapting their technique to new findings in the literature, surgeons seem to perform the technique for which they were trained and are most comfortable, and are unwilling to change their practice patterns.

Overall, the number of procedures between 1995 and 2002 remained stable, followed by a distinct decrease in numbers in 2003 and 2004. Most studies analyzing the development of laparoscopic fundoplication show a marked increase until the late 1990s, followed by a plateau phase or a moderate decline in numbers [16, 19–22, 28]. No study, to our knowledge, has analyzed the years after 2000 and, therefore, the present analysis adds to the current scientific literature.

The number of procedures performed in Switzerland (Swiss population: approximately 7.3 million) is low compared with other European countries with a similar-sized population. In Sweden with a population of approximately 8.8 million, 1,300 procedures were performed in 1997 [19]. In Finland with a population of approximately 5 million, more than 700 fundoplications were performed in

1993 [20]. In comparison, the maximal number of fundoplications per year in our prospective database was 131 in 2001. This figure does not reflect all fundoplications performed in Switzerland, because approximately 30% of hospitals and surgeons did not contribute their cases to the prospective SALTS database. However, even after adjusting for noncontributing surgeons, the number of fundoplications performed in Switzerland was considerably lower than in other European countries. One possible reason for this difference is the fact that in Switzerland upper endoscopies are normally performed by gastroenterologists rather than surgeons. This may influence the choice of treatment toward medical proton pump inhibitors and decrease the number of patients referred to a surgeon. Other reasons may be the generally accepted safety and excellent low side-effect profile of proton pump inhibitors and the higher threshold for Swiss patients to undergo surgery. Additionally, there are substantial differences in reimbursement practices in the different national health systems, which may influence the patient's choice of treatment. A number of studies showed that restrictions in reimbursement of specific proton pump inhibitors resulted in a change of utilization patterns [29–31]. However, whether a more restrictive reimbursement policy for proton pump inhibitors increases the number of patients choosing surgery has yet to be evaluated.

Regardless of procedure, a significant trend toward shorter total and postoperative length of stay was found in the present investigation. Both decreased by approximately 2 days. The length of stay was rather long compared with the literature with an average of 2 days postoperative length of stay [11, 28, 32]. This might be related to specific socioeconomic reasons in Switzerland with patients tending to stay a few days longer in the hospital than medically indicated.

Duration of surgery also decreased significantly during the time period, which is consistent with the literature and most likely related to the individual and institutional learning curves [33, 34].

There was a trend toward lower intraoperative and postoperative morbidity over time. Our complication rates are comparable with the literature [15, 18]. Although the difference in conversion rates between early years (1995–1999) and late years (2000–2004) was significant, there was only a trend toward significance for intraoperative and postoperative morbidity. This was, however, not statistically significant due to the low number of events. The conversion rate decreased significantly from 6% in 1995 to virtually 0%, consistent with recent reports [33, 34].

In the present investigation, patients who underwent Nissen or Toupet procedures did not differ with respect to age, gender, or ASA score. Intraoperative and postoperative complication rates were similar as was the reoperation rate. Interestingly, a significant difference was detected in total and postoperative LOS because patients who underwent Toupet procedures were discharged 1 day earlier. One possible explanation might be the onset of dysphagia immediately after surgery, which delays discharge. The occurrence of early postoperative onset of dysphagia in Nissen fundoplications has been described repeatedly [10, 24]. In most patients, however, this symptom disappears within a few weeks.

Limitations and strengths

We acknowledge that there are limitations of this investigation. First, this study is most limited by the lack of long-term data. For instance, we were unable to ascertain the incidence of long-term dysphagia or the need for reoperation. Further research is needed to assess the long-term advantages and potential drawbacks of the laparoscopic Toupet versus Nissen fundoplication. Second, there is a possibility of underreporting of negative outcomes. However, it can be safely assumed that the rate of underreporting would have been constant over the years and that there would be no difference in reporting of outcomes between patients who underwent Nissen versus Toupet. Underreporting would seem unlikely to influence the trend analysis or the comparison of the two procedures.

This study has several strengths: (1) the sample size is large compared with clinical studies published in the literature; (2) the data, which were prospectively gathered, are very complete; and (3) this study is population-based and thus has excellent generalizability [35]. Although this study was based on Swiss patients only, we believe that the results can be generalized to other European countries as well as to North America, where the standard of laparoscopic surgery is high. Finally and most importantly, this is the first trend analysis that assesses clinical outcomes after laparoscopic fundoplication over time and the first to analyze the trends in laparoscopic fundoplications in the twenty-first century.

Conclusions

This study shows that the use of laparoscopic Nissen versus Toupet fundoplications remained stable over time, indicating that reports of advantages of one procedure over the other have minimal influence on surgeons' choice of technique. There was a trend toward shorter length of hospital stay, shorter duration of surgery, less complications, and conversions over the 10-year time period. No differences with respect to short-term outcomes were found between patients who underwent Toupet versus Nissen fundoplications except a shorter length of hospital stay in the former group.

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