

SURGICAL TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE: total or partial fundoplication?

Systematic review and meta-analysis

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ABSTRACT – *Context* - Although the high incidence of gastroesophageal reflux disease (GERD) in the population, there is much controversy in this topic, especially in the surgical treatment. The decision to use of a total or partial fundoplication in the treatment of GERD is still a challenge to many surgeons because the few evidence found in the literature. *Objective* - To bring more clear evidence in the comparison between total and partial fundoplication. *Data sources* - A systematic review of the literature and meta-analysis with randomized controlled trials accessed from MEDLINE, LILACS, Cochrane Controlled Trials Database was done. The outcomes remarked were: dysphagia, inability to belch, bloating, recurrence of acid reflux, heartburn and esophagitis. For data analysis the odds ratio was used with corresponding 95% confidence interval. Statistical heterogeneity in the results of the meta-analysis was assessed by calculating a test of heterogeneity. The software Review Manager 5 (Cochrane Collaboration) was utilized for the data gathered and the statistical analysis. Sensitive analysis was applied using only trials that included follow-up over 2 years. *Results* - Ten trials were included with 1003 patients: 502 to total fundoplication group and 501 to partial fundoplication group. The outcomes dysphagia and inability to belch had statistical significant difference ($P = 0.00001$) in favor of partial fundoplication. There was not statistical difference in outcomes related with treatment failure. There were no heterogeneity in the outcomes dysphagia and recurrence of the acid reflux. *Conclusion* - The partial fundoplication has lower incidence of obstructive side effects.

HEADINGS – Gastroesophageal reflux, surgery. Fundoplication. Review. Meta-analysis.

INTRODUCTION

The gastroesophageal reflux disease (GERD) is one of the diseases that have the strongest impact in the society nowadays. It is responsible for the major costs in the treatment of the gastrointestinal diseases in USA⁽²⁹⁾ with low scores of quality of life^(9, 27).

In the mild cases of GERD, the clinical management is most indicated; however, the surgical treatment is a good option in severe forms and in young patients who do not want to take tablets for the rest of their lives.

In 1956, Rudolf Nissen⁽²⁵⁾ first described the 360° fundoplication, believing that this procedure increases the pressure in the lower esophageal sphincter. Until nowadays, this is the most performed surgical treatment in GERD, because the good long-term results in the control of the acid reflux. However, are related high levels of post-operative dysphagia in these patients⁽³⁵⁾.

An alternative for the total fundoplication was the creation of partial fundoplications. Toupet in 1963⁽³⁴⁾, created a posterior partial fundoplication with 180° circumference. After him, other surgeons created many others partial fundoplications looking to reduce the post-operative dysphagia⁽¹⁹⁾, but the long-term results showed a rate of recurrence of the reflux higher than the Nissen procedure⁽¹⁷⁾.

Many studies comparing total and partial fundoplications started to appear in the literature, but most of them failed to show a significant difference^(24, 38). Recently, a meta-analysis was published showing that both procedures have a good control of the reflux, but with low incidence of dysphagia in the partial fundoplication group, however, the methodological quality of the included studies was very poor⁽³⁵⁾.

The aim of this study is to bring a more clear evidence for this question, through a systematic review and meta-analysis, with a rigorous methodological quality assessment.

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METHODS

This systematic review and meta-analysis was performed in the Gastro-surgery post-graduation program of the Universidade Federal de São Paulo, Cochrane Center of Brazil, and Researching, Learning and Extension Unity of Hospital Munir Rafful, Volta Redonda, RJ, Brazil and had approval by the Ethics Research Committee of this institution. The research followed the recommendations of the Cochrane Collaboration and the methodological quality was evaluated by the QUORUM statement check-list.

The search strategy was performed following the recommendation of the Cochrane Handbook for Systematic Reviews of Interventions version 5.0.1., in the MEDLINE, LILACS and the Cochrane Collaboration Trials Register (CTTR) electronic databases; annals of congresses, banks of thesis and references of the primary studies. The following Medical Subject Heading (MeSH) and/or text words were used: “gastroesophageal reflux”, “fundoplication”, “Nissen”, “partial”; associated with the Cochrane highly sensitive search strategy for RCTs⁽⁴⁰⁾ (Figure 1).

Nº	Terms and combinations utilized
#1	Cochrane highly sensitive search strategy for RCTs
#2	MH gastroesophageal reflux or Tw gastroesophageal reflux or Ti gastroesophageal reflux
#3	Fundoplication or Nissen or partial
#4	#2 and #3
#5	#1 and #4

FIGURE 1. Search strategy in electronic data basis
 RCTs = Randomized controlled trials; MH = Medical headings;
 Tw = Text words; Ti = English title

Only randomized clinical trials (RCT) were included, and their quality was measured by the CONSORT check-list and by a randomization classification (Figure 2). Only RCTs with “A” classification were included. Studies that contained children, patients with severe esophageal dysmotility and other techniques that we can not classified as total or partial fundoplication were excluded. If a trial had subsequent publications of the same casuistic, we considerate the last analysis of each outcome in the follow-up.

Randomization classification	
A	Correct randomization
B	Non-specified
C	Incorrect randomization
D	Non-randomized

FIGURE 2. Randomization classification (Cochrane Handbook for Systematic Reviews of Interventions version 5.0.1)

The following outcome parameters were analyzed: dysphagia, recurrence of acid reflux, bloating, inability to belch, esophagitis and heartburn. The outcomes dysphagia, bloating, inability to belch and heartburn were analyzed

by validated scales in the primary studies. As well, we only consider the results of the outcomes esophagitis and recurrence of reflux when they were evaluated by endoscopic and pHmetric exams, respectively.

Data were collected from the selected studies and inserted in the Review Manager Software version 5. The statistical method used was the Mantel-Haenszel test, considering a *P* value less than 0.05 statistically significant. Summary statistics were calculated using the odds ratio (OR) and associated 95% confidence intervals (CI) in the fixed model. Heterogeneity was tested using the Cochrane Chi-Square statistic and the degree of freedom to calculate the *I*², and assumed to be present when *I*² was less than 50%. We also performed a subgroup analysis of the outcomes parameters dysphagia and recurrence of acid reflux in studies with follow-up higher than 2 years. Publication bias was tested using a funnel plot in the outcomes dysphagia and recurrence of acid reflux.

RESULTS

Seventeen RCTs were found with the search strategy (Figure 3). Three studies were excluded by exclusion criteria: one study in children⁽¹⁰⁾, one comparing Hill fundoplication⁽⁷⁾ and another that not include the principal outcomes studied⁽⁶⁾. Four studies were excluded by low methodological quality^(14, 18, 33, 36). At the end, 10 RCTs were selected (Figure 4).

The partial fundoplication resulted in a less incidence of obstructive effects compared with the total fundoplication. There was a significant difference in post-operative dysphagia in favor of the partial fundoplication with *P* value <0.0001 and OR = 0.46 with CI: 0.32–0.66 (Figure 5). In the outcome inability to belch, we found similar results with *P*<0.0001 and OR = 0.47 with CI: 0.33–0.67 (Figure 6). However, we did not found statistically difference in gas bloating, with a *P* value = 0.18 and OR = 0.78 with CI: 0.54–1.13 (Figure 7).

In the outcomes related with treatment failure, we did not find any statistical difference between partial and total fundoplication. In the pooled results of the outcome recurrence of acid reflux, we found a *P* value of 0.77 with OR = 1.10 and CI: 0.59 – 2.05 (Figure 8). When we analyzed the outcome heartburn, we found a *P* value of 0.34 with OR = 1.22 with CI: 0.81–1.86 (Figure 9). The analysis of the outcome esophagitis results in a *P* value of 0.74 with OR = 1.12 and CI: 0.56–2.25 (Figure 10).

In the subgroup analysis in studies with follow-up higher than 2 years, we found similar results as the overall analysis: the outcome dysphagia results in a *P* value of 0.03 with OR = 0.56 and CI: 0.33–0.95 (Figure 11), and the outcome recurrent reflux shows a *P* value of 0.39 with OR = 0.76 and CI: 0.42–1.41 (Figure 12). We did not found significant heterogeneity in none of the pooled analysis of the outcomes.

We considerate the chance of publication bias in the outcome dysphagia because the heterogeneous distribution of the trials in the funnel-plot (Figure 13). In the outcome recurrence of acid reflux, we found a homogeneous distribution of the trials; however, we can not analyze the chance of bias because the few number of studies (Figure 14).

Trial	Type of access	Total fundoplication (n = 502)	Partial fundoplication (n = 501)	Type of partial fundoplication	Follow-up
Segol et al. ⁽³⁰⁾	Open	18	16	180° posterior	2 years
Lundell et al. ^(21, 22)	Open	54	56	180° posterior	11 years
Hagedorn et al. ⁽¹⁵⁾					
Watson et al. ⁽³⁷⁾					
Ludemann et al. ⁽²⁰⁾	Laparoscopic	48	41	180° anterior	10 years
Cai et al. ⁽⁴⁾					
Fibbe et al. ⁽¹²⁾					
Zornig et al. ⁽³⁹⁾	Laparoscopic	50	50	180° posterior	2 years
Strate et al. ⁽³²⁾					
Watson et al. ⁽³⁸⁾	Laparoscopic	52	60	90° anterior	6 months
Baigrie et al. ⁽¹⁾	Laparoscopic	84	79	180° anterior	2 years
Spence et al. ⁽³¹⁾	Laparoscopic	39	40	90° anterior	1 year
Mickevicius et al. ⁽²⁴⁾	Laparoscopic	64	63	180° posterior	1 year
Booth et al. ⁽³⁾	Laparoscopic	59	58	180° posterior	1 year
Khan et al. ⁽¹⁶⁾	Laparoscopic	34	38	270° posterior	1 year

FIGURE 3. Included studies in the systematic review and their characteristics

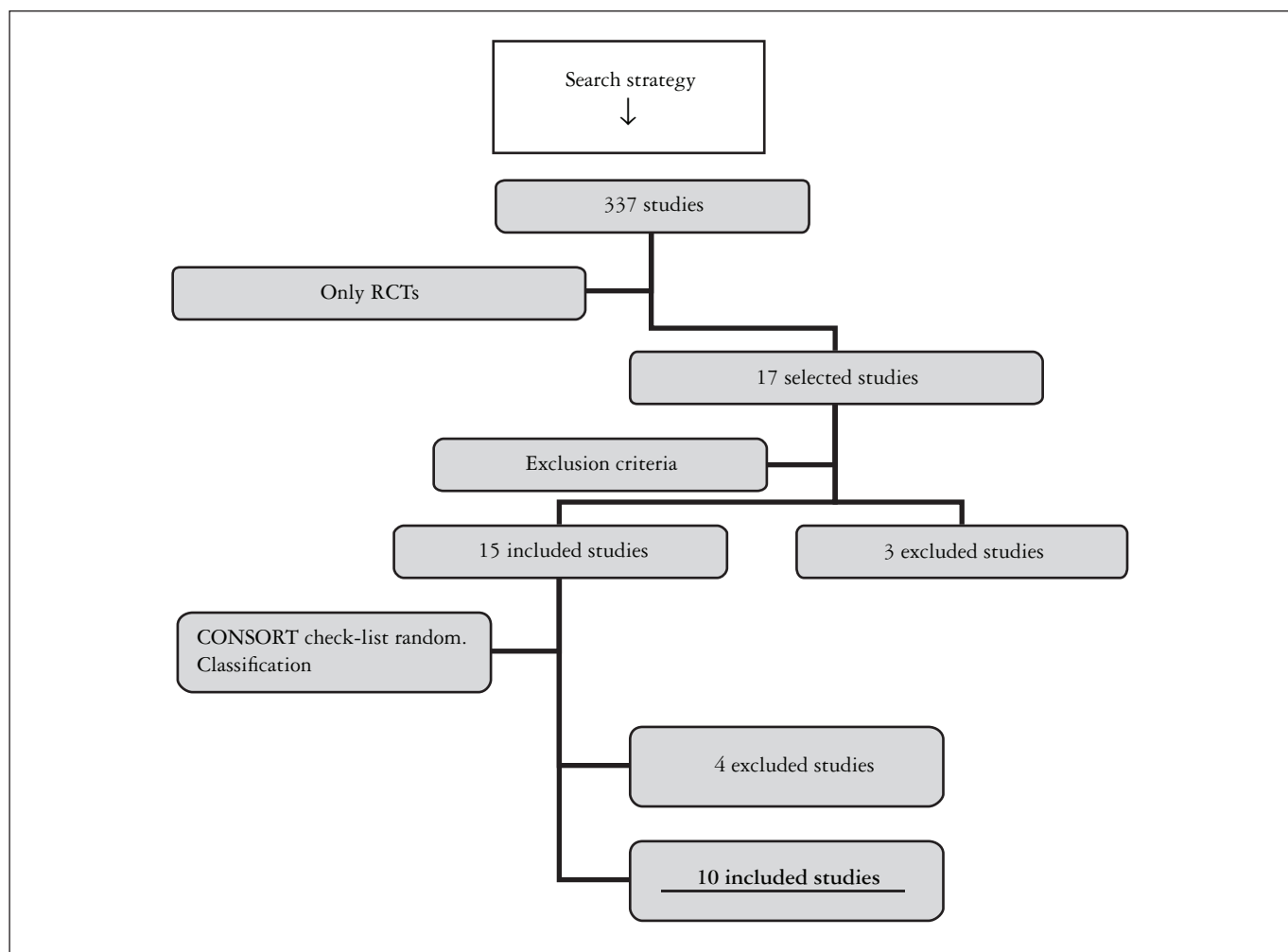


FIGURE 4. Study methodology diagram according with QUORUM statement checklist. RCT indicated randomized clinical trial

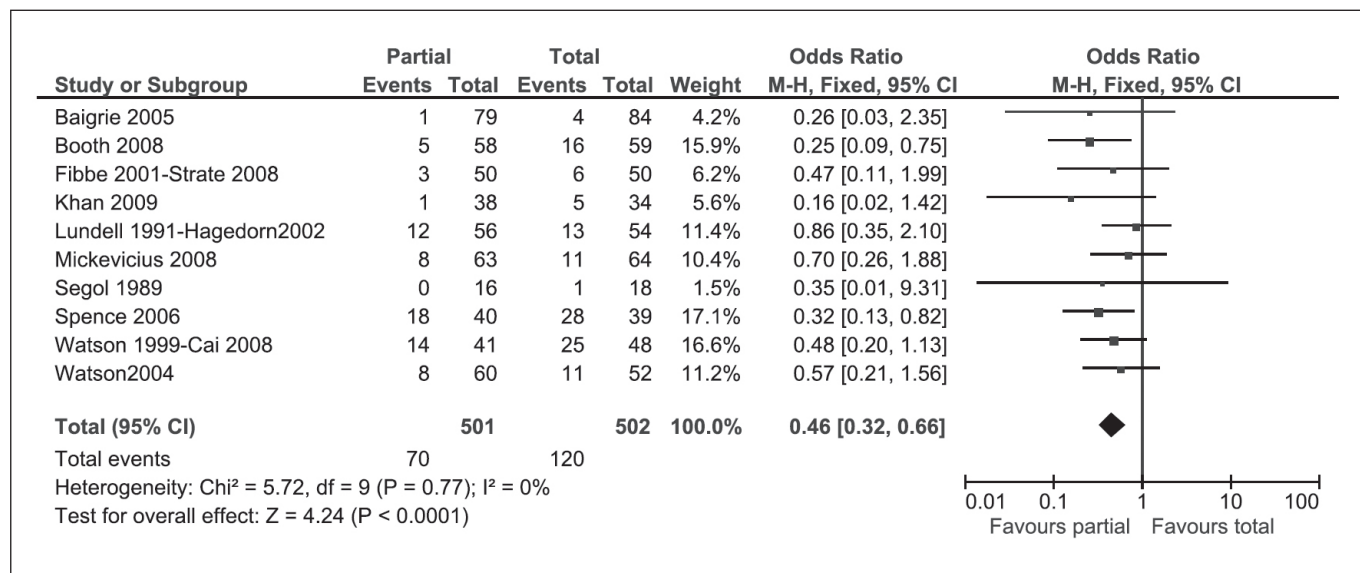


FIGURE 5. Graphic showing the meta-analysis of the 10 studies comparing partial and total fundoplications in GERD. Presentation of results of postoperative dysphagia, by OR, with CI of 95%

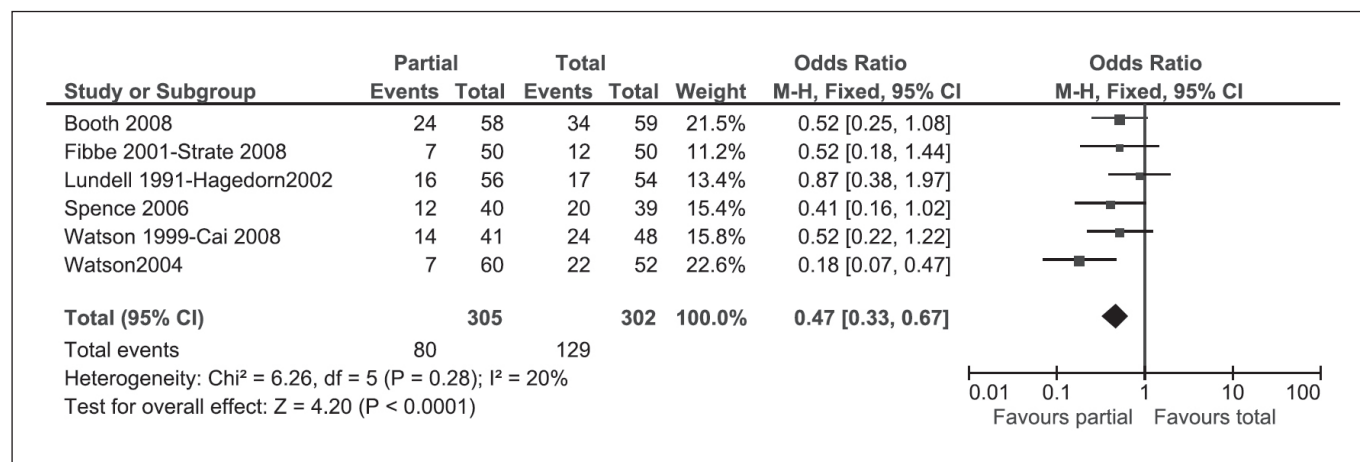


FIGURE 6. Graphic showing the meta-analysis of the six studies comparing partial and total fundoplications in GERD. Presentation of results of inability to belch, by OR, with CI of 95%

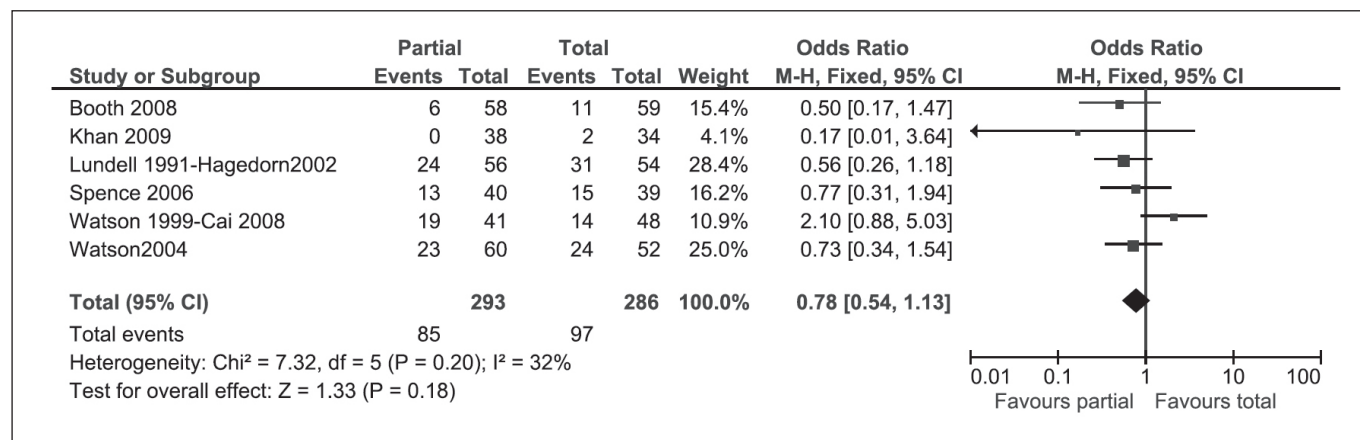


FIGURE 7. Graphic showing the meta-analysis of the six studies comparing partial and total fundoplications in GERD. Presentation of results of gas bloating, by OR, with CI of 95%

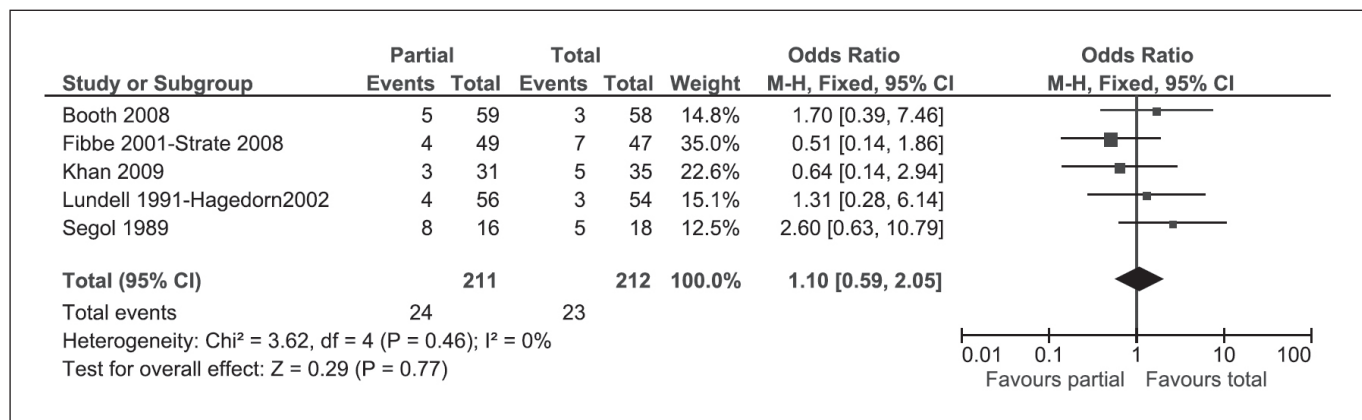


FIGURE 8. Graphic showing the meta-analysis of five studies comparing partial and total fundoplications in GERD. Presentation of results of recurrence of acid reflux, by OR, with CI of 95%

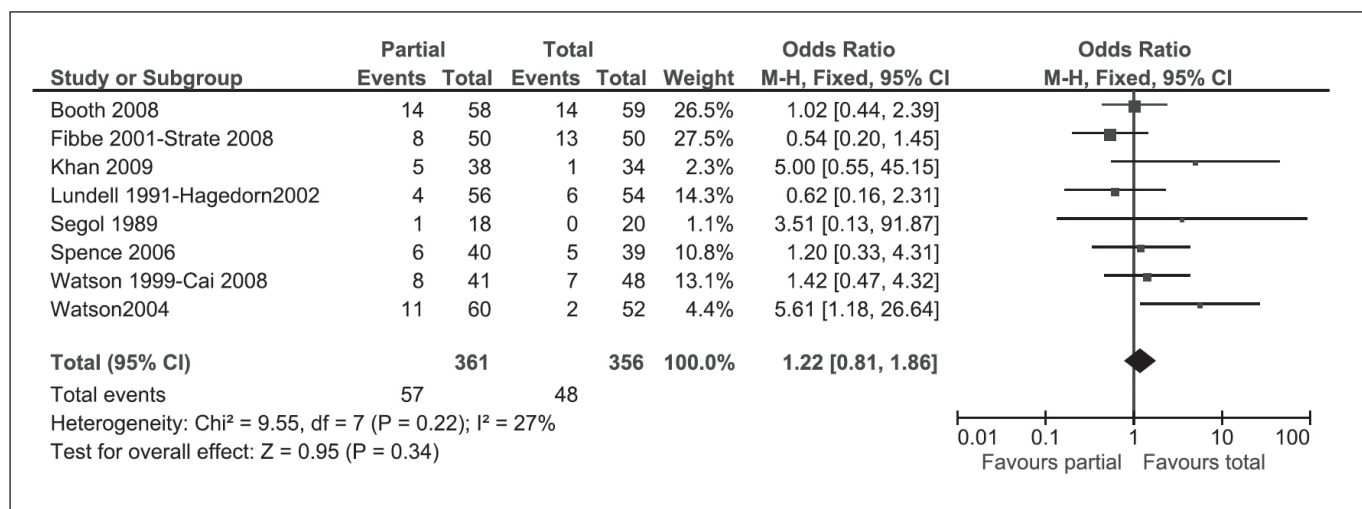


FIGURE 9. Graphic showing the meta-analysis of eight studies comparing partial and total fundoplications in GERD. Presentation of results of heartburn by OR, with CI of 95%

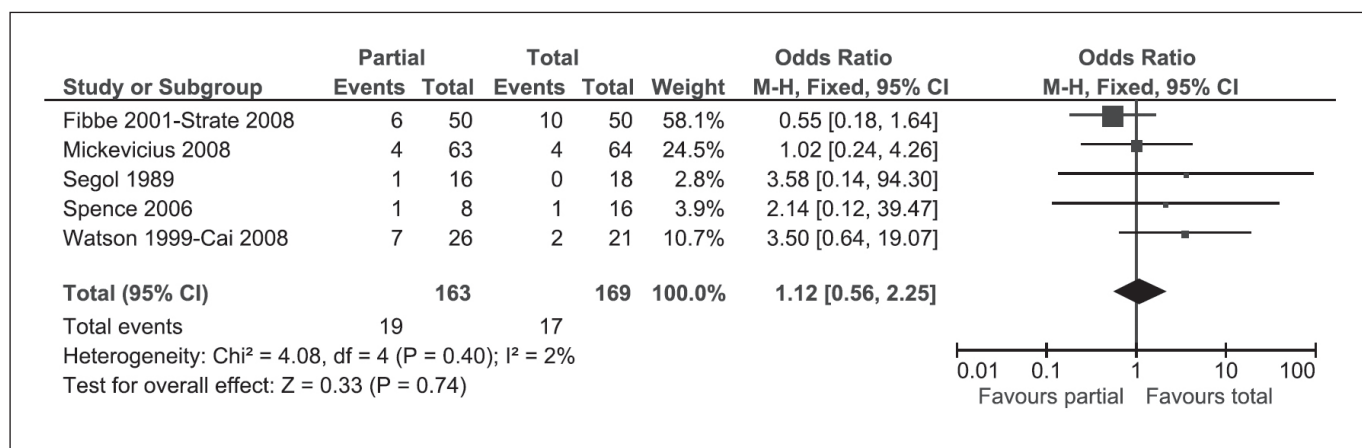


FIGURE 10. Graphic showing the meta-analysis of five studies comparing partial and total fundoplications in GERD. Presentation of results of esophagitis by OR, with CI of 95%

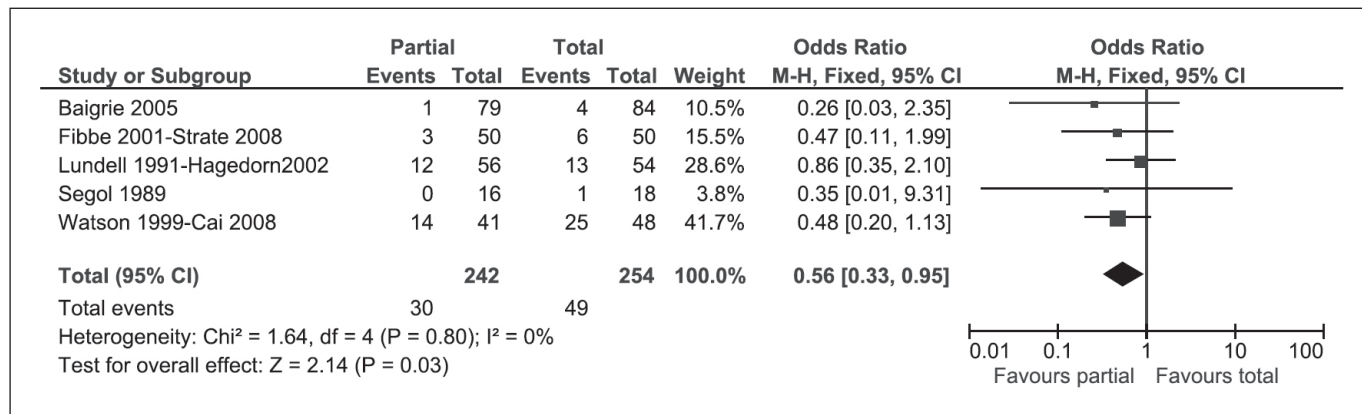


FIGURE 11. Graphic showing the meta-analysis of five studies comparing partial and total fundoplications with follow-up >2 years in GERD. Presentation of results of dysphagia by OR, with CI of 95%

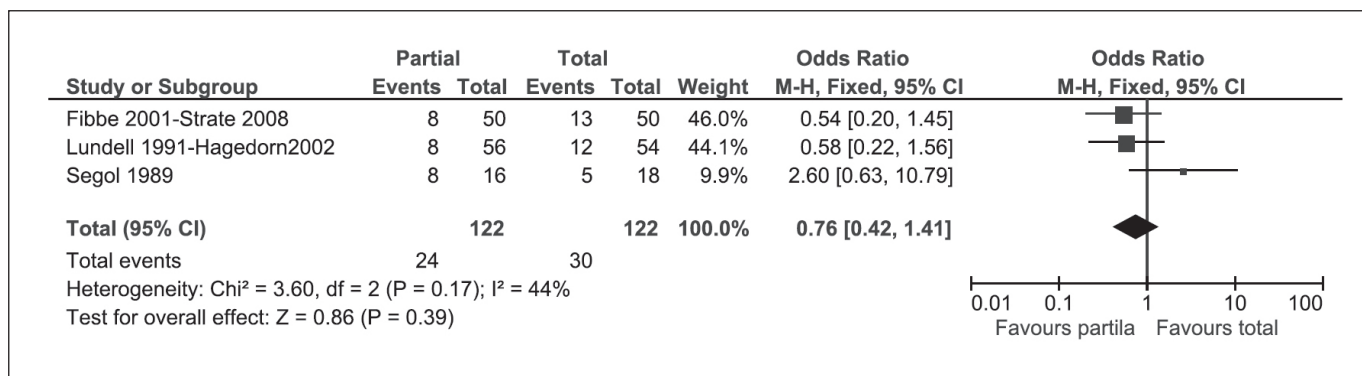


FIGURE 12. Graphic showing the meta-analysis of three studies comparing partial and total fundoplications with follow-up >2 years in GERD. Presentation of results of recurrence of acid reflux by OR, with CI 95%

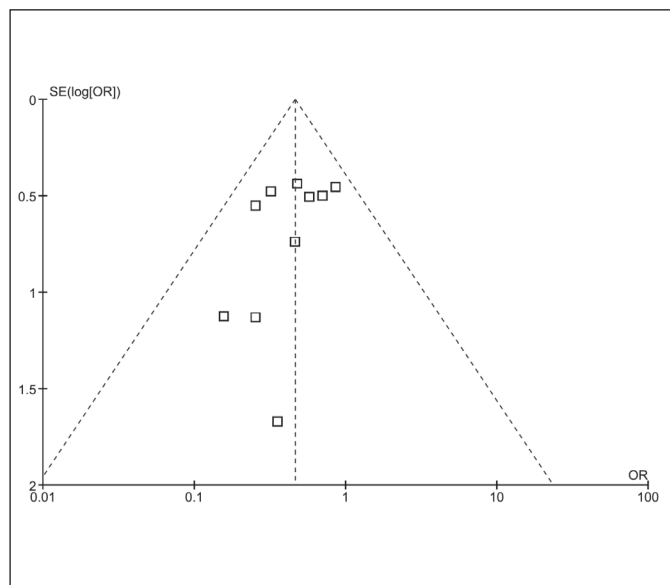


FIGURE 13. Funnel – plot graphic showing 10 studies comparing partial and total fundoplications in order to detect publication bias in the outcome dysphagia

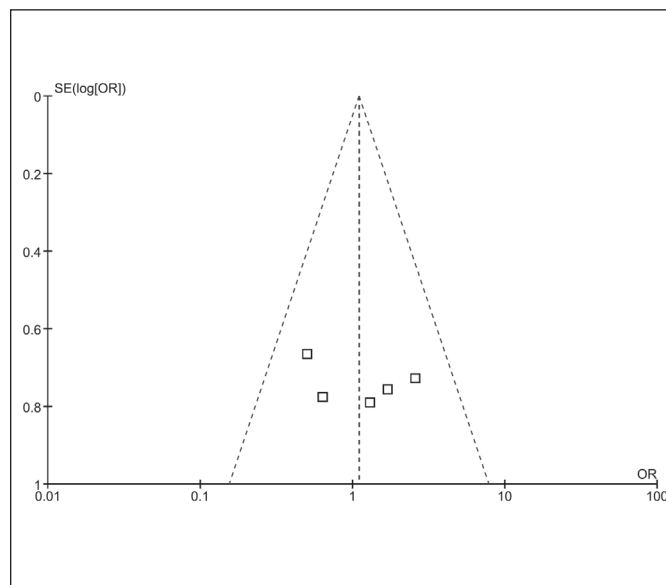


FIGURE 14. Funnel – plot graphic showing five studies comparing partial and total fundoplications in order to detect publication bias in the outcome recurrent reflux

DISCUSSION

The anti-reflux surgery is the one of most controversial topics in gastroenterological surgery, especially in choice of total or partial fundoplications in GERD. In a few decades ago, this decision was made according to manometric finds in the pre-operative exam, believing that patients with abnormal esophageal motility had a higher chance to develop post-operative dysphagia⁽¹³⁾. However, subsequent randomized studies failed to confirm this hypothesis⁽²⁸⁾.

The search for better evidence about this subject is growing along this decade. Catarci et al.⁽⁵⁾, in a systematic review with meta-analysis, analyzed nine studies comparing total and partial fundoplications: six with open and three with laparoscopic access. They did not find any statistical difference between the groups in the outcomes dysphagia and recurrence of acid reflux. Recently, another systematic review with meta-analysis⁽³⁵⁾ was published with 11 studies included. A lower incidence of obstructive effects as dysphagia was found with statistical difference, with no difference in treatment failure parameters.

Although the Varin et al.⁽³⁵⁾ study followed the Cochrane Collaboration recommendations and used the QUORUM statement check-list, there are important considerations to make. As the Catarci et al.⁽⁵⁾ study, the methodological quality of the included studies was very poor, and most of these studies dated from the early of the 90 decade, when the laparoscopy was in the beginning. Other relevant points are the unclear outcome measures and statistical analysis, as detection of publication bias.

We believe that the path to find a more clear evidence of this subject is the adoption of a more rigorous methodology in the systematic review with meta-analysis. We decided to include only RCTs with adequate parameters of randomization, as sequence generation, allocation concealment and blinding. We also adopted explicit criteria of outcome measures. For example, many studies reported recurrence of acid reflux; however, most of them are not clear in the method to find this outcome. We decide only to include studies that measured this outcome by pHmetric exam, in order to standardize this analysis.

An interesting point that we observed in our meta-analysis is the fact that only two included studies show significant statistical difference in the outcome dysphagia^(3, 31). However, when the meta-analysis is done, we found a high statistical difference in this outcome. Although the higher incidence of recurrent acid reflux in follow-up of partial fundoplications studies^(2, 17), we did not find statistical difference in the RCTs and in the meta-analysis. These aspects show the importance of the systematic review and meta-analysis in find more accurate evidence. According to our results in the subgroup analysis with studies with follow-up longer than 2 years, both techniques have good control of the reflux in long-term. In our results, partial fundoplications have less dysphagia events than total fundoplication, however the meta-analysis “diamond” is

closer the base line in the subgroup with longer follow-up than in the analysis with all 10 studies. It made us think the possibility to, having more studies with longer follow-up, the incidence of dysphagia were the same in both techniques. Maybe in a future actualization of this review, we will have the answer.

Some authors believe that the higher incidence of obstructive symptoms in the total fundoplication is caused by some technical aspects during the operative act. RCTs comparing total fundoplication with and without division of short gastric vessels can not show any statistically significant difference in the outcome dysphagia⁽¹¹⁾. The use of intraesophageal bougies and the confection of a floppy and short valve seems to be effective in reduce dysphagia^(8, 26), but there are not much trials with methodological quality to confirm theses hypothesis.

Although the more rigorous methodology adopted, our review still have some important limitations. The most of the included studies have a short follow-up and the outcome measures are still unclear. Systematic reviews with meta-analysis are limited by the data included in the RCTs, and the difficulties in the conduction of these kinds of studies, makes that, sometimes, they have poor methodology, especially in the surgical area⁽²³⁾. At last, we can not make the meta-analysis in some continuous outcomes, as the post-operative measure of lower esophageal sphincter tonus, because the lack of data.

Another important problem found in systematic reviews is the publication bias, which is caused by the results of a trial being more likely to be published if a statistically significant benefit of treatment is found. This kind of bias is best avoided by improved literature searching, however, there are some useful diagnostic plots and statistics available that can help detect it, as funnel plots. Without publication bias, this plot should be funnel shaped, with homogeneous distribution of the “positive” and “negative” trials. Unfortunately, this technique requires a large number of trials (10 at least) with a spread of sizes to provide an adequate funnel. In our study, we accepted the possibility to occur publication bias in the outcome “dysphagia”, but we do not have enough studies to make a conclusion in the outcome “recurrence of acid reflux”. Despite these results, we still think that is always important to perform a strategy to detect the publication bias, because it has important influence in the overall results in systematic reviews and meta-analysis.

With the present review, we can conclude that partial fundoplication can be a good choice in the surgical treatment GERD, with lower rates of obstructive side effects than total fundoplication.

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RESUMO – Contexto - Apesar da alta incidência da doença do refluxo gastroesofágico (DRGE) na população em geral, ainda existe muita controvérsia sobre este assunto, especialmente quanto ao tratamento cirúrgico. A decisão de usar fundoplicatura total ou parcial no tratamento da DRGE ainda é um desafio para muitos cirurgiões devido à pouca evidência disponível na literatura. **Objetivo** - Comparar a fundoplicatura total e as fundoplicaturas parciais no tratamento da DRGE, avaliando a eficácia das duas técnicas operatórias. **Método** - Foram utilizadas a revisão sistemática da literatura e metanálise de estudos prospectivos e randomizados. Fontes de informação utilizadas: LILACS, MEDLINE, Cochrane Controlled Clinical Trials Database. A metanálise foi realizada utilizando-se o programa de informática da Colaboração Cochrane (Review Manager 5.0.1) e o cálculo dos desfechos foi feito pela razão de chances, com respectivo intervalo de confiança de 95%. Os desfechos estudados foram: disfagia, dificuldade em eructar, plenitude gástrica, recorrência do refluxo ácido, pirose e esofagite. Análise de subgrupo: estudos com seguimento maior que 2 anos. **Resultados** - Foram selecionados 10 ensaios clínicos, onde 1003 doentes foram estudados, sendo 502 alocados para o grupo fundoplicatura total e 501 locados para o grupo fundoplicatura parcial. Os desfechos contínuos não puderam ser calculados em razão da falta de dados. Somente os desfechos disfagia e dificuldade em eructar tiveram resultados estatisticamente significantes ($P < 0.0001$) a favor da fundoplicatura parcial. **Conclusão** - A fundoplicatura parcial está relacionada com a menor incidência de eventos obstrutivos pós-operatórios.

DESCRITORES – Refluxo gastroesofágico, cirurgia. Fundoplicatura. Revisão. Metanálise.

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