LAPAROSCOPIC CHOLECYSTECTOMY VERSUS MINILAPAROTOMY IN CHOLELITHIASIS: SYSTEMATIC REVIEW AND META-ANALYSIS

ABSTRACT - Introduction: A introduction da técnica laparoscópica em 1985 foi um fator importante na colecistectomia por representar técnica menos invasiva, resultado estético melhor e menor risco cirúrgico comparado ao procedimento laparotômico. Aim: To compare laparoscopic and minilaparotomy cholecystectomy in the treatment of cholelithiasis. Methods: A systematic review of randomized clinical trials, which included studies from four databases (Medline, Embase, Cochrane and Lilacs) was performed. The keywords used were “Cholecystectomy”, “Cholecystectomy, Laparoscopic” and “Laparotomy”. The methodological quality of primary studies was assessed by the Grade system. Results: Ten randomized controlled trials were included, totaling 2043 patients, 1020 in Laparoscopy group and 1023 in Minilaparotomy group. Laparoscopic cholecystectomy dispensed shorter length of hospital stay (p<0.00001) and return to work activities (p<0.00001) compared to minilaparotomy, and the minilaparotomy shorter operative time (p<0.00001) compared to laparoscopy. Laparoscopy decrease the risk of postoperative pain (NNT=7) and infectious complications (NNT=50). There was no statistical difference between the two groups regarding conversion (p=0.06) and surgical reinterventions (p=0.27), gall bladder’s perforation (p=0.98), incidence of common bile duct injury (p=1.00), surgical site infection (p=0.52) and paralytic ileus (p=0.22). Conclusion: In cholelithiasis, laparoscopic cholecystectomy is associated with a lower incidence of postoperative pain and infectious complications, as well as shorter length of hospital stay and time to return to work activities compared to minilaparotomy cholecystectomy.

INTRODUCTION

Cholelithiasis is one of the most common digestive tract diseases and constitutes an important health problem in developed countries. It is estimated that 10-15% of the adult population accounting for 20 to 25 million americans have or will have gallstones1. The third National Health and Nutrition Assessment estimates that 6.3 million of men and 14.2 millions of women aged between 20 and 74 years in the United States had gallbladder disease7. Besides the problems related to health, cholelithiasis also brings significant costs, estimated at around 6.2 million dollars annually in the same country12.

About 750,000 patients undergo cholecystectomy per year in the United States, and the number of surgical procedures has grown increasingly over the years, with the purpose to avoid the symptoms, complications and recurrence of gallstones in the biliary tract11. In Brazil, cholelithiasis is the most common abdominal surgical disease in elderly patients, its incidence being associated with the progression of age, with an overall prevalence in the general population of 9.3%13. In the last two years in the Unified Health System, according to the Datasus, conventional cholecystectomy represents 88% of the surgeries, compared to 12% of laparoscopic cholecystectomy2, this probably explains why the distribution of equipment and offer of services related to the procedure is quite uneven.
being the most modern techniques adopted in a limited number of countries, and most of these have neither the technology nor the qualified professional for this procedure, but in the private sector in Brazil, it is clear an absolute predominance of laparoscopic cholecystectomy over the conventional cholecystectomy during the whole period (90% or more of total).1

The introduction of the laparoscopic technique in 1985, first made by Mühe was an important factor for the large increase in the cholecystectomy, since it represented a less invasive technique, generated better esthetic result and provided a lower surgical risk compared to the conventional procedure.12

Dubois and Barthelot introduced in 1982, minimally invasive technique for conventional cholecystectomy, the minilaparotomy cholecystectomy,6 and Tyagi et al, in 1994, described a new technique for minimally invasive cholecystectomy, and this has recently challenged the role of laparoscopic cholecystectomy.2,8

This review aims to compare laparoscopic and minilaparotomy cholecystectomy in the treatment of cholelithiasis regarding perioperative complications, length of hospital stay, surgical time, incidence of reoperation and conversion to open surgery and time for returning to labor activities.

METHODOLOGY

Identification and selection of studies

A search of electronic literature was done through the database MEDLINE, EMBASE, COCHRANE, and LILACS. On Medline and Embase the combination of terms (Cholecystectomy) and (Cholecystectomy, Laparoscopic) and (Laparotomy) were utilized. On LILACS and Cochrane, the keywords used were: (Cholecystectomy) and (Laparoscopy) and (Laparotomy). Manual searches were done among study references found. The searches ended on July 5, 2013.

The articles were selected independently and in pairs, by reading the titles and abstracts. Any difference between the articles was resolved by consensus.

Inclusion and exclusion criteria

Inclusion criteria: 1) randomized controlled trials; 2) comparison between laparoscopic and minilaparotomic cholecystectomy in cholelithiasis; 3) analysis of at least one of the outcomes described below; 4) a clear description of the surgical indication.

Exclusion criteria: 1) non-randomized trials, cohort, case-control and case report; 2) outcomes of interest not reported for both surgical techniques; 3) failure to provide data for performing at least one calculation in the meta-analysis; 4) studies that correspond to the same sample and identical study authors.

Outcomes analyzed

They were length of hospital stay, operative time, surgical conversion, reoperation, time to return to labor activity and perioperative complications, divided into: 1) intraoperative complications (perforation of the gallbladder and common bile duct injury); and 2) postoperative complications (surgical site infection, pain, postoperative ileus, infectious complications).

Methodological quality and statistical analysis

The methodological quality of the primary studies was evaluated by the GRADE system proposed by the Grades of Recommendation, Assessment, Development and Evaluation group.4

The meta-analysis was performed with the Review Manager 5.2 program. Data were evaluated by intention-to-treat, meaning the patients that did not undergo the proposed intervention or patients lost in follow-up during the study were considered as clinical outcome.

The evaluation of the dichotomous variables was performed by the difference in absolute risk (RD) adopting a 95% confidence interval. When there was a statistically significant difference between the groups, the number needed to treat (NNT) or the number needed to cause harm (NNH) was calculated. The continuous variables were evaluated by the difference in means (MD). Studies that did not show data in terms of means and their respective standard deviations were not included in the analyses.

Heterogeneity and sensitivity analysis

Inconsistencies among the clinical studies were estimated using the chi-squared heterogeneity test and quantified using I². A value above 50% was considered substantial. Studies that generated heterogeneity were represented by funnel plots.

RESULTS

Study selection

In total, 2071 articles (Medline=900; Embase=1135; Cochrane=3 and Lilacs=27) were retrieved through the electronic searches. In manual search no articles were found in addition to the previously selected on the bases cited. After using methodological filter Randomized Controlled Trial, 77 articles remained for analysis by title and abstracts. Sixty-seven were excluded for not comparing laparoscopic and minilaparotomy cholecystectomy. Thus, in this review were included in the analysis ten randomized clinical trials (Figure 1).

Description of included studies

The ten studies included randomized patients into two groups, laparoscopy and minilaparotomy, totaling 2043 patients, 1020 in the laparoscopy group and 1023 in the minilaparotomy group (Table 1).

Methodological quality

Evaluation of methodological quality of the selected studies performed by GRADE system include 11 questions that were answered as: Y=yes; N=no; ND=not described (no information enabling the evaluation).

The questions and answers according to each study were: 1) was the study randomized? Y for all; 2) was the allocation of patients to groups confidential? N to Velázquez-Mendoza (2012) and Y for the rest; 3) were patients analyzed in the groups to which they were randomized (was the analysis by intention to treat)? Y for all; 4) were patients in
TABLE 1 – Description of included studies

| Name               | Year of publication | Patients (n) | Laparoscopy | Minilaparotomy | Outcomes                                                                 |
|--------------------|---------------------|--------------|-------------|----------------|--------------------------------------------------------------------------|
| Velázquez-Mendoza25| 2012                | 88           | 43          | 45             | Bleeding; surgical site infection; perforation of the gallbladder; hepatic injury; postoperative ileus; postoperative pain |
| Harju23            | 2010                | 60           | 31          | 29             | Infection; common bile duct injury; bleeding                              |
| Keus22             | 2007                | 257          | 120         | 137            | Inflammation; abscess; pancreatitis; common bile duct injury; fistula; time to return to labor activity |
| Vaghas24           | 2006                | 88           | 44          | 44             | Fever; hernia; pneumonia; postoperative ileus; time to return to labor activity |
| Harju23            | 2006                | 157          | 72          | 85             | Surgical site infection; pneumonia; ITU; fistula                          |
| Srivastava22       | 2001                | 100          | 59          | 41             | Fistula; surgical site infection; wound with pus; pain                   |
| Ros19              | 2001                | 724          | 362         | 362            | Subphrenic collection; surgical site infection; urinary retention; bile duct injury; chest infection; time to return to labor activity |
| Majeed16           | 1996                | 200          | 100         | 100            | Infection; hematoma; urinary retention; ITU; sepsisemia; incisional hernia; IAM; chest infection; fistula; pain; bridža’s obstruction; postoperative bleeding |
| McMahon16          | 1994                | 302          | 151         | 148            | Surgical site infection; perforation of the gallbladder; postoperative ileus; pain |
| Barkun7            | 1992                | 70           | 38          | 32             |                                                                        |

ITU=urinary tract infection; IAM=acute myocardial infarction
both groups similar with respect to the previously known prognostic factors? Y for all; 5) was the study blind? ND to Vagenas (2006) Harju (2006), Srivastava (2001), McMahon (1994) and Barkun (1992) and Y for the remainder; 6) except the experimental intervention, were the groups treated equally? Y for all; 7) were the losses significant? ND to Vagenas (2006) Harju (2006) and Srivastava (2001) and N for the remaining; 8) did the study have a precision estimate for the effects of treatment? Y for all; 9) are the study patients similar to those of interest? Y for all; 10) are the outcomes of the study clinically relevant? Y for all; 11) were the potential conflicts of interest declared? ND for all.

Outcomes analyzed
Length of hospital stay
Four studies analyzed the primary outcome length of hospital stay; however, due to the high heterogeneity (MD -0.79 CI95% -0.90 a -0.68; p<0.00001 e I²=67%) related to the study of Majeed (1996), was chosen to exclude it from the analysis. The new forest-plot showed a mean difference between groups of 0.82 (CI95% -0.94 a -0.71; p<0.00001 e I²=0%). Thus, laparoscopy dismissed shorter hospital stay compared to minilaparotomy (Figure 2).

Surgical time
Seven primary studies analyzed the outcome surgical time; however, the studies Majeed (1996) and Vagenas (2006) promoted high heterogeneity (MD 31.83; CI95% 30.33 a 33.32; p<0.00001 e I²=96%) and were excluded from the initial forest-plot. Thus, the difference in mean between groups was 15.51 (CI95% 12.20 a 18.81; p<0.00001 e I²=43%), and that the minilaparotomy dismissed shorter surgical time compared to laparoscopy (Figure 3).

Surgical conversion
Nine primary studies analyzed the outcome surgical conversion. The conversion was defined: laparoscopy-laparotomy and minilaparotomy-laparotomy. There was no

FIGURE 2 - Meta-analysis of the mean difference in length of hospital stay between laparoscopy and minilaparotomy in patients with cholelithiasis

| Study of Subgroup | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI |
|-------------------|------|----|-------|------|----|-------|--------|-----------------|
| Keus 2007         | 2.4  | 4.6| 120   | 3.1  | 12.4| 137   | 0.3%   | -0.70 [-2.93, 1.53] |
| Majeed 1996       | 3.6  | 2.3| 100   | 3.5  | 2.1 | 100   | 0.0%   | 0.10 [-0.51, 0.71] |
| Ros 2001          | 2.6  | 3.3| 362   | 3.2  | 362 | 362   | 3.4%   | -0.60 [-1.23, 0.03] |
| Vagenas 2006      | 2.28 | 0.14| 44    | 3.11 | 0.37| 44    | 96.3%  | -0.83 [-0.95, -0.71] |
| Total (95% CI)    | 526  |    | 543   | 100% |    |       | -082 [-0.94, 0.71] |

Heterogeneity: Chi²=0.51, df=2 (P=0.77); I²=0%; Test for overall effect: Z=13.91 (P<0.00001)

FIGURE 3 - Meta-analysis of the mean difference in surgical time between laparoscopy and minilaparotomy in patients with cholelithiasis pacientes com coleciotilase

| Study of Subgroup | Mean | SD | Total | Mean | SD | Total | Weight | IV, Fixed, 95% CI |
|-------------------|------|----|-------|------|----|-------|--------|-----------------|
| Barkun 1992       | 85.9 | 32 | 32    | 73.1 | 24.5| 32    | 6.2%   | 12.80 [-0.45, 26.05] |
| Harju 2006        | 79   | 27 | 72    | 55   | 19.5| 85    | 19.5%  | 24.00 [16.51, 31.49] |
| Majeed 1996       | 69.2 | 24.6| 100   | 45.4 | 19.8| 100   | 0.0%   | 23.80 [17.61, 29.99] |
| McMahon 1994      | 71   | 20 | 151   | 57   | 24  | 148   | 43.5%  | 14.00 [8.99, 19.01] |
| Ros 2001          | 108  | 45 | 362   | 94   | 45  | 362   | 25.5%  | 14.00 [7.44, 20.56] |
| Vagenas 2006      | 101.3| 4.99| 44    | 64.32| 3.13| 44    | 0.0%   | 36.98 [35.24, 38.72] |
| Velázquez-Mendoza 2012 | 86.04 | 42.25| 43| 79.02 | 23.68| 45 | 5.3% | 7.02 [-7.938, 21.42] |
| Total             | 666  |    | 672   | 100% |    |       | 15.51 [12.20, 18.81] |

Heterogeneity: Chi²=6.99, df=4 (P=0.14); I²=43%; Test for overall effect: Z=9.19 (P<0.00001)
statistically significant difference between the two groups (RD \(-0.03; CI95\% -0.06 a 0.00; p=0.06; I^2=66\%).

**Surgical reintervention**

Three primary studies analyzed the surgical reintervention. There was no statistically significant difference between the two groups (RD \(-0.01; CI95\% -0.02 a 0.01; p=0.27; I^2=0\%).

**Time to return to labor activity**

Four studies analyzed the primary endpoint time to return to labor activity; however, studies of Ros (2001) and Vagenas (2006) showed high heterogeneity (MD 1.11; CI95\% 0.73 a 1.48; \(p<0.00001\) e \(I^2=98\%\) being excluded from the analysis. Thus, the mean between groups was 0.49 (CI95\% 0.04 a 0.93; \(p=0.03\) e \(I^2=0\%\)) demonstrating that laparoscopy dismissed less time to return to labor activity compared to minilaparotomy (Figure 4).

**Intraoperative complications**

**Gallbladder perforation**

Three primary studies analyzed the gallbladder perforation; however, the study of Ros (2001) promoted high heterogeneity (RD 0.11; CI95\% 0.06 a 0.16; \(p<0.0001\) e \(I^2=91\%\)), being excluded from the analysis. In the construction of the new forest-plot can be seen that there was no statistically significant difference between the two groups (RD \(-0.00; CI95\% -0.05 a 0.05; p=0.98; I^2=13\%).

**Injury to the common bile duct**

Four primary studies analyzed the outcome common bile duct injury. There was no statistically significant difference between the two groups (RD \(-0.00; CI95\% -0.01 a 0.01; p=1.00; I^2=0\%).

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### Meta-analysis of the time to return to labor activity between laparoscopy and minilaparotomy in patients with cholelithiasis

#### Study of Subgroup

| Study of Subgroup | Laparoscopy | Laparotomy | Mean difference |
|------------------|-------------|------------|----------------|
| Keus 2007        | 4.1         | 2.3        | 120            |
| Majeed 1996      | 4.3         | 3.8        | 100            |
| Ros 2001         | 11.5        | 8.1        | 362            |
| Vagenas 2006     | 10.68       | 1.59       | 44             |
| Total            | 220         | 237        | 100            |

Heterogeneity: \(\chi^2=0.35, df=1\) (\(p=0.55\)); \(I^2=0\%\); Test for overall effect: \(Z=2.13\) (\(p=0.03\)).

**FIGURE 4** - Meta-analysis of the time to return to labor activity between laparoscopy and minilaparotomy in patients with cholelithiasis

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### Meta-analysis of the incidence of infectious complications between laparoscopy and minilaparotomy in patients with cholelithiasis

#### Study of Subgroup

| Study of Subgroup | Laparoscopy | Laparotomy | Risk difference |
|------------------|-------------|------------|----------------|
| Barkun 1992      | 1           | 38         | 0.00           |
| McMahon 1994     | 40          | 151        | 148            |
| Ros 2001         | 226         | 362        | 298            |
| Srivastava 2001  | 0           | 59         | 1               |
| Velázquez-Mendoza 2001 | 30        | 43         | 29             |
| Total (95\% CI)  | 513         | 510        | -0.18 (-0.23, -0.13) |
| Total events     | 266         | 357        |                |

Heterogeneity: \(\chi^2=1.08, df=1\) (\(p=0.30\)); \(I^2=7\%\); Test for overall effect: \(Z=6.46\) (\(p=0.00001\)).

**FIGURE 5** - Meta-analysis of the incidence of postoperative pain between laparoscopy and minilaparotomy in patients with cholelithiasis

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### Meta-analysis of the incidence of infectious complications between laparoscopy and minilaparotomy in patients with cholelithiasis

#### Study of Subgroup

| Study of Subgroup | Laparoscopy | Laparotomy | Risk difference |
|------------------|-------------|------------|----------------|
| Harju 2006       | 0           | 72         | 85             |
| Keus 2007        | 2           | 120        | 1              |
| Majeed 1996      | 2           | 100        | 100            |
| McMahon 1994     | 1           | 151        | 8               |
| Ros 2001         | 6           | 362        | 14              |
| Vagenas 2006     | 0           | 44         | 2               |
| Total (95\% CI)  | 729         | 739        | 100            |
| Total events     | 9           | 28         |                |

Heterogeneity: \(\chi^2=6.07, df=4\) (\(p=0.19\)); \(I^2=34\%\); Test for overall effect: \(Z=3.09\) (\(p=0.002\)).

**FIGURE 6** - Meta-analysis of the incidence of infectious complications between laparoscopy and minilaparotomy in patients with cholelithiasis
ARTIGO DE REVISÃO

DISCUSSÃO

O primeiro caso de colecistectomia foi feito por Carl Langenbuch em 1882, que acreditava na ideia de que a prevenção da colecistite poderia ocorrer se ela não fizesse a galinha, mas sim que ela era "síndrome". Após isso, a técnica de colecistectomia aberta foi popularizada através de grandes incisões laparóticas. Em 1985, Erich Mühe em Böblingen, Alemanha, realizou a primeira colecistectomia laparoscópica (LC), que se tornou um procedimento dominante no tratamento de colecistite na era da endoscopia.

No entanto, um dos maiores desafios da Laparoscopia é a incisão de laparotomia, que pode variar de 8 a 10 cm. Isso resulta em um tempo de cirurgia maior e um tempo de hospitalização maior. Além disso, a regra de trabalho também é mais longa. Outro fator importante é a taxa de conversão cirúrgica. A taxa de conversão cirúrgica em colecistectomia laparoscópica é geralmente mais alta do que em colecistectomia aberta.

No entanto, os poucos estudos que compararam os resultados de Laparoscopia e colecistectomia aberta não encontraram resultados significativos. Por exemplo, Purkayastha et al. (2007) compararam os resultados de Laparoscopia e colecistectomia aberta e não encontraram diferença significativa na taxa de regras de trabalho ou tempo de hospitalização.

A Laparoscopia também tem algumas desvantagens, como a necessidade de instrumentos especializados e pessoal qualificado. Além disso, a Taxa de conversão cirúrgica também é mais alta. No entanto, a Laparoscopia tem vantagens, como menores cicatrizes e tempo de recuperação.

CONCLUSÃO

A colecistectomia laparoscópica é associada a uma menor incidência de complicações pós-operatórias e infecções. No entanto, o tempo de recuperação é mais longo em comparação com a colecistectomia aberta. Portanto, a decisão de qual técnica usar deve ser baseada no caso individual e no tipo de cirurgia.

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