



RATIONALE AND DESIGN OF A R.C.T COMPARING TRANSUMBILICAL LAPAROSCOPIC CHOLECYSTECTOMY VS. STANDARD 4-PORT LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Background: Single-incision laparoscopic cholecystectomy is developed with the aim of decreasing post-operative pain and improving cosmesis. Several retrospective studies have shown feasibility of the technique. However, randomized trials comparing single-incision to multiple-incision laparoscopic cholecystectomy are not enough.

AIM: The aim of our study is to compare the results of using the transumbilical laparoscopic cholecystectomy (TLC) vs. standard laparoscopic cholecystectomy (SLC) with respect to complications, operating time, postoperative pain, use of analgesics, length of stay, return to work, rate of incisional hernia, cosmetic outcome and etc.

Patients and methods: Between May'2012 and May'2015, 110 patients will be randomized to TLC group and SLC group. The results of both methods will be compared with a number of indicators such as operating time, postoperative pain, use of analgesics, length of stay, complications, etc.

Key words: transumbilical laparoscopic cholecystectomy (TLC), standard laparoscopic cholecystectomy (SLC)

INTRODUCTION

In 1985 - Erich Mühe - performed the first laparoscopic cholecystectomy. [1] Laparoscopic cholecystectomy has been the gold standard for removal of the gallbladder since the early 1990s. [2] As technology has progressed, surgeons have begun to develop less invasive methods for this commonly performed procedure. In 1992 - Pelosi - performed the first laparoscopic appendectomy through a single-skin incision. [3] In 1997 - Navarra - performed the first LC with single transumbilical incision. [4] Single-incision laparoscopic cholecystectomy (SILC) is emerging as a potentially less invasive alternative to standard laparoscopic cholecystectomy. There are studies comparing different aspects of advantages and disadvantages of both methods. Some researchers have suggested that the TLC is with significantly less postoperative pain,

reduces the hospital stay, excellent cosmetic results and longer operating time than conventional laparoscopic cholecystectomy. [5, 6, 7, 8] Other authors reported there are no differences in hospital length of stay, blood loss, complication rates, or pain scores between SILC and LC. [9]

But the lack of sufficient objective data to show the advantages and disadvantages of each method, puts the problem of the need for randomized, controlled trial comparing the results of both methods with the following design:

PATIENTS AND METHODS

Criteria:

Inclusion Criteria:

- 18 Years and older;
- Indications for planned cholecystectomy;
- Information agreement;

Exclusion Criteria:

- Precede operations in URQ;
- Pregnancy;

Studied parameters:

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A. Operative time:

- To cut d.cysticus a.cystica;
- Gallbladder extraction;
- Total;

2. Intraoperative complications:

- Bleeding;
- lesion of extrahepatic biliary tree ;
- lesion of gallbladder;
- Other;

3. Postoperative complications:

- Wound infection;
- Intra-abdominal collection;
- Other;

4. Postoperative period:

- Pain and need for analgetics;
- Nausea and vomiting;
- Restoration of the passage;
- Laboratory tests - CRP and IL-6;

- Postoperative stay - when the patient believes he is ready to be dehospitalized;

- 5. Patient satisfaction with the cosmetic result;
- 6. Is it important for the patient the number of scars;

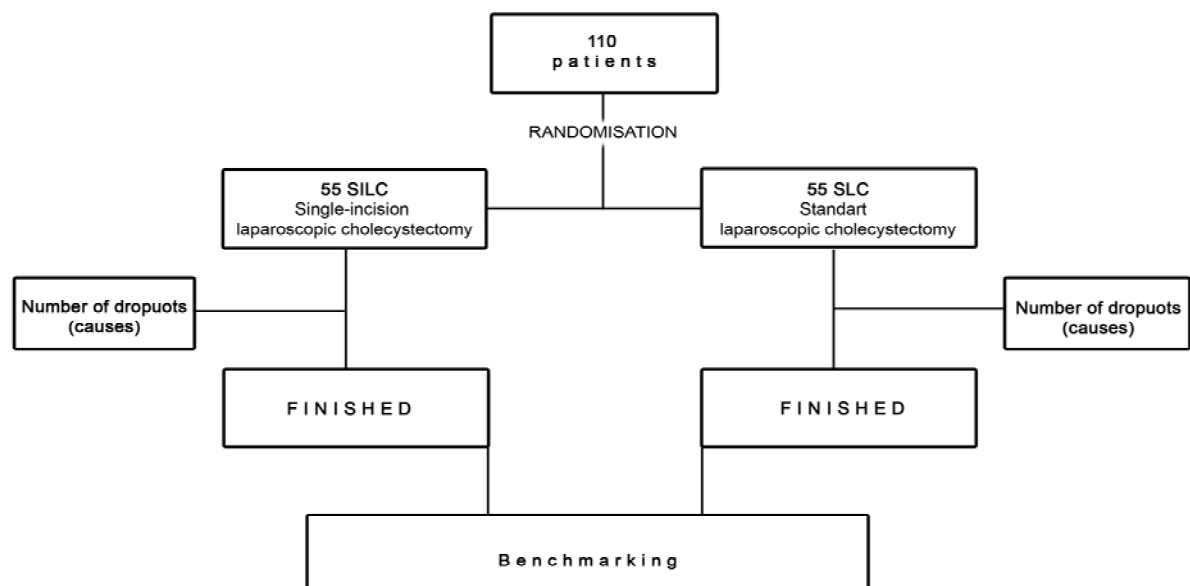
- 7. Costs of operation;

8. Laboratory tests:

- Pre - operative - blood cell count, Gluc, Urea, Creat, PT, aPPT, fibrinogen, ASAT, ALAT, TBIL, DBIL, AF, GGT, CRP, IL-6;
- Postoperative - CPR - 8, 24 and 48h after surgery; IL-6-24 and 48h after surgery;

9. Late results:

- Umbilical hernia;
- Extrahepatic biliary tree strictures;
- Other;



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