ORIGINAL ARTICLE

A randomised, single blinded trial, assessing the effect of a two week preoperative very low calorie diet on laparoscopic cholecystectomy in obese patients

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Abstract

Background: Laparoscopic cholecystectomy (LC) can be technically challenging in the obese. The primary aim of the trial was to establish whether following a Very Low Calorie Diet (VLCD) for two weeks pre-operatively reduces operation time. Secondary outcomes included perceived operative difficulty and length of hospital stay.

Methods: A single-blinded, randomized controlled trial of consecutive patients with symptomatic gallstones and BMI >30 kg/m^2 46 patients were randomized to a VLCD or normal diet for two weeks prior to LC. Food diaries were used to document dietary intake. The primary outcome measure was operation time. Secondary outcomes were length of stay, weight change operative complications, day case rates and perceived difficulty of operation.

Results: The VLCD was well tolerated and had significantly greater preoperative weight loss (3.48 kg vs. 0.98 kg; $p < 0.0001$). Median operative time was significantly reduced by 6 min in the VLCD group (25 vs. 31 min; $p = 0.0096$). There were no differences in post-operative complications, length of stay, or day case rates between the groups. Dissection of Calot's triangle was deemed significantly easier in the VLCD group.

Conclusion: A two week VLCD prior to elective laparoscopic cholecystectomy in obese patients is safe, well tolerated and was shown to significantly reduce pre-operative weight and operative time.

Trial registration: ISRCTN: 61630192. http://www.isrctn.com/ISRCTN61630192 Trial registration.

Received 19 December 2015; accepted 14 January 2016

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Introduction

Gallstone disease is increasingly common pathology and 10–15% of adults will develop gallstones in their lifetime.[1] Most patients with gallstones are asymptomatic, however between 1 and 4% of patients develop symptoms and complications each year.[1] Laparoscopic cholecystectomy is now the treatment of choice for symptomatic gallstone disease[2,3] and is now the most common elective abdominal operation performed in the western world,[4] with over 40,000 performed in the UK every year.[5] Minimally invasive surgery is associated with reduced post-operative pain, shorter hospital stay and earlier return to normal activities and can be performed as a day case.[6] The National Health Service (NHS) in the United Kingdom has introduced an incentive scheme to improve day case rates for laparoscopic cholecystectomy. The main factors preventing same day discharge are operative complications, post-operative pain control and nausea and vomiting.[7]

A high body mass index (BMI) is a strong risk factor for the development of gallstones.[8–10] Adult obesity is defined by the World Health Organization as BMI greater than 30 kg/m^2

Historically, obesity has been considered a relative contraindication for laparoscopic cholecystectomy.[11] However with increasing experience, the success and safety of laparoscopic procedures in obese patients is now comparable to the non-obese patient and may be of particular benefit in this population as they are more prone to operative and post-operative complications following open surgery.[11,12] Laparoscopic cholecystectomy in obese patients still presents technical challenges and the operation time remains significantly longer.[11] There is increased abdominal wall adiposity which increases the length of time for port placement and hinders abdominal wall compliance during the procedure. Other problems in the obese can include poor exposure to Calot's triangle because of an enlarged steatotic left hepatic lobe, excess intra-abdominal fat and a more friable, fatty liver which is prone to bleeding.[6,11,13]

In bariatric surgery, access to the gastro-oesophageal region is hampered by an enlarged, fatty left lobe of the liver.[13] A very low calorie diet (VLCD) can significantly reduce liver volume by mobilizing hepatic glycogen and water stores.[14] The reduction in pre and post-operative liver size in response to VLCD has been demonstrated on ultrasound[13] and magnetic resonance imaging.[15] The effect of VLCD has been shown after two weeks[16] and is a recommendation of the Society of American Gastrointestinal and Endoscopic Surgeons for preparation prior to bariatric surgical procedures.[17]

The aim of this study is to examine the effect of a two week VLCD on laparoscopic cholecystectomy in obese patients. The VLCD is a previously well used diet based on commercially available low calorie shakes (Slimfast). The aim of the diet is to provide a balanced diet with a daily target of 800 kcal. We hypothesize that the reduction in size of the liver will improve surgical access and dissection, reduce operation complexity and ultimately operating time. By reducing operative difficulty, we propose that there will be a reduction in procedure related complications and an increase in the number of day case laparoscopic cholecystectomies.

Materials and methods

This was a single centre, blinded, prospective, randomized controlled trial (REC number 10/H0305/78). The study design adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[18] Consecutive patients attending for elective laparoscopic cholecystectomy at the Norfolk and Norwich University Hospital, United Kingdom between May 2011 and May 2013 were eligible for recruitment. Inclusion criteria were adult patients with capacity to consent, a body mass index (BMI) over 30 kg/m^2 and symptomatic gallstone disease. Exclusion criteria were the presence of any pre-existing liver disease, Diabetes Mellitus, confirmed common bile duct stones or previous abdominal surgery. Randomisation was achieved using a computer generated random numbers program at the surgical pre-assessment clinic by one of the research team not involved in the surgery (KB,RL, NB). A single upper gastrointestinal surgeon (ML) performed all cases and was blinded to the intervention group throughout the study period (Fig. 1). The anaesthetic regime was the same for each patient and the anaesthetist was also blinded from the treatment group. All patients underwent routine intraoperative cholangiography.

Randomisation was performed using a computer-generated random number list (Microsoft Excel) with the necessary information (very low calorie diet or control group) being sealed in numeric order envelopes by someone independent of the study. After written consent was obtained the next number envelope was opened and the patient told which group they fall into. If they were allocated to the low calorie arm participants were given a diet sheet to follow. The VLCD comprised a two week calorie-restricted diet aiming for a total calorific intake of 800 Kcal/day (please see attached Supplementary diet sheet). Dietician advice was available to both arms of the study. All patients were asked to complete a detailed dietary survey for the two weeks prior to surgery.

The primary outcome measure of this study was operative time, measured from first incision to end of skin closure. Secondary outcomes were weight change from pre-operative clinic to the day of procedure, post-operative complications, length of stay and day-case rates. The perceived difficulty of the procedure was assessed at the end of each operation by the surgeon. The ease of technical aspects of the procedure were evaluated using a semi-qualitative scale (1 = very difficult, 2 = difficult, 3 = normal, 4 = easy).

A sample size calculation carried out prior to the trial commencing determined that 46 patients were required to detect an operative time difference of 2.5 min at 80% power and 95% confidence intervals. Data were analysed using GraphPad Prism version 6. Data were assessed for normality using the D'Agostino-Pearson test and tested with non-parametric (Mann–Whitney test) and parametric tests (Unpaired t-test, two tail) as appropriate. Day case rates were assessed with Fisher's exact test. $p < 0.05$ was considered significant.

Results

Between May 2011 and May 2013, 77 patients met the inclusion criteria and were invited to participate in the study. 31 patients declined to take part resulting in 46 patients (21 cases and 25 controls) being randomized for inclusion. There were no baseline differences between the control and treatment groups (Table 1). In the control group 21 patients presented with biliary colic, two with cholecystitis and two with obstructive jaundice. In the treatment group 19 patients presented with biliary colic and two with cholecystitis. All patients were followed up for the length of the trial, one patient in the control arm did not complete a diet sheet but still consented for participation in the study analysis.