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PRELIMINARY RESULTS OF META-ANALYSIS OF LAPAROSCOPIC AND OPEN INGUINAL HERNIA REPAIR

Matthew John Burstow
Department of Surgery, Ipswich Hospital, Queensland, Australia
E-mail: mjburstow@gmail.com

Rossita Mohamad Yunus
Department of Mathematics and Computing, Australian Centre for Sustainable Catchments, University of Southern Queensland, Toowoomba, Queensland, Australia
E-mail: yunus@usq.edu.au

Shahjahan Khan
Department of Mathematics and Computing, Australian Centre for Sustainable Catchments, University of Southern Queensland, Toowoomba, Queensland, Australia
E-mail: khans@usq.edu.au

Breda Memon
Department of Surgery, Ipswich Hospital, Queensland, Australia
E-mail: bmemon@yahoo.com

Muhammed Ashraf Memon
Department of Surgery, Ipswich Hospital, Queensland, Australia
Department of Surgery, University of Queensland, Herston, Queensland, Australia
Faculty of Medicine and Health Sciences, Bond University, Gold Coast, Queensland, Australia
Faculty of Health Science, Bolton University, Bolton, Lancashire, UK
E-mail: mmemon@yahoo.com

ABSTRACT

Purpose: The aim was to conduct a meta-analysis of the randomized evidence to determine the relative merits of laparoscopic inguinal herniorrhaphy (LIHR) and open inguinal herniorrhaphy (OIHR).

Data Sources and Review Methods: A search of the Medline, Embase, Science Citation Index, Current Contents and PubMed databases identified all randomized clinical trials (RCTs) that compared LIHR and OIHR published in the English literature between January 1990 and January 2007. The six outcome variables analysed were operating time, hospital stay, return to normal activity, return to work, total complications and recurrence rate. Random effects meta-analyses were performed using odds ratios and weighted mean differences.

Results: Fifty-nine trials were considered suitable for the meta-analysis. A total of 8092 patients underwent LIHR and 8580 had OIHR. For three of the six outcomes the summary point estimates favoured LIHR over OIHR; there was a significant reduction of 34% in the relative odds of postoperative complications, 4.99 days in time to return to normal activity and 6.39 days

in time to return to work. However, there was a significant increase of 14.08 min in the mean operating time for LIHR. The relative odds of short term recurrence increased by 20 percent for LIHR compared with OIHR. There was a small trend towards decreased duration of hospital stay for LIHR compared with OIHR, although these results were not statistically significant.

Conclusions: Based on this meta-analysis, LIHR offers patients a number of benefits over OIHR at the expense of longer operating time but comparable recurrence rate and hospital stay.

Keywords: Hernia; Inguinal; Comparative study; Prospective studies; Randomized controlled trials; Random allocation; Clinical trial; Human; English

1. INTRODUCTION

Since Bassini introduced the prototypical inguinal hernia repair in 1887, there has been continuous development and refinement related to this surgical procedure. There has been a move away from sutured repairs to tension-free techniques employing mesh with subsequent improvements in recurrence rates and surgical morbidity (Brooks et al., 2007). Early sutured repairs had a recurrence rate as high as 15%, with newer methods this has been reduced to under 5% (Brooks et al., 2007). With the advent of laparoscopic surgery, new techniques became available to apply to the inguinal hernia repair. The success of the laparoscopic cholecystectomy led proponents to argue that the application of minimally invasive surgical techniques to inguinal hernia repair would decrease recovery time and post operative pain (Felix and Michas, 1993; Filipi et al., 1992; Fitzgibbons et al., 1994; Ger et al., 1993; Mckernan and Laws, 1993). Studies to date have largely supported this premise, however recurrence rates, singled out as the most important outcome by some authors, vary widely (see table 1). Meta-analyses comparing LIHR and OIHR have generally shown that LIHR has advantages over OIHR in providing shorter hospital stay, faster return to work and normal activities and fewer overall complications (Kuhry et al., 2006; McCormack, et al., 2003; Memon, et al., 2003; Schmedt et al., 2004; Voyles et al., 2002). However LIHR takes significantly longer to perform, is more expensive per case and shows a trend towards increased recurrence rates versus the open procedure (Kuhry et al., 2006; McCormack et al., 2003; Memon et al., 2003; Schmedt et al., 2004; Voyles et al., 2002).

This meta-analysis is an update to that already published by Memon et al. (2003) examined RCTs comparing LIHR and OIHR, with a total of 59 trials included. The Quality of Reporting of Meta-analyses (QUOROM) statement was followed in the preparation of this study (Moher et al., 1999).

2. METHODS

RCTs that compared LIHR with any type of OIHR, and were published in full in peer-reviewed journals in the English language between January 1990 and the end of Jan 2008, were included. Unpublished studies and abstracts presented at national and international meetings were excluded. Published studies that reported three or fewer outcome variables or that contained insufficient information were also excluded, but only after an effort had been made to obtain unpublished or missing data from the original authors. Trials were identified by conducting a comprehensive search of Medline, Embase, Science Citation Index, Current Contents and PubMed databases, using medical subject headings ‘hernia’, ‘inguinal’, ‘comparative study’, ‘prospective studies’, ‘randomized controlled trials’, ‘random allocation’ and ‘clinical trial’. Manual search of the bibliographies of relevant papers was also carried out to identify trials for possible inclusion. Data extraction and critical appraisal were carried out by three authors, who also contacted the original authors of some of the trials for clarification of data and to obtain unpublished, missing or additional information on various outcome measures. The response to

this was extremely good. Six outcome variables were considered most suitable for analysis: operating time, time to discharge from hospital, return to normal activity and return to work, postoperative complications and hernia recurrence rate. Other outcome measures, such as postoperative pain, analgesia requirements and hospital costs, were excluded owing to variations in reporting methodology and the inability to devise uniform objective analysis of these outcomes. The quality of the randomized clinical trials was assessed using Jadad's scoring system (Jadad et al., 1996).

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3. STATISTICAL ANALYSIS

Meta-analyses were performed using odds ratios (ORs) for binary and weighted mean differences (WMDs) for continuous outcome measures (Sutton et al., 2000). Random effects models were used to combine the data and statistical heterogeneity was assessed using the $\chi 2$ test. To assess whether heterogeneity was explained by study-level co-variates (year of study, length of follow-up and size of study) a random effects meta-regression model was used (Thompson and Sharp, 1998). Subgroup analyses were performed by comparing the results of the two methods of LIHR (transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP)) and OIHR (tension free and tension creating) separately (Sutton et al., 2000). A sensitivity analysis was carried out to assess the impact of study quality on the results, by identifying poor-quality studies (Jadad score <1) (Jadad et al., 1996). Funnel plots were synthesized in order to determine the presence of publication bias in the meta-analysis. All estimates were obtained using a computer program written in R, and all plots were obtained using the meta-package (Vienna: R Foundation for Statistical Computing, 2008; Lumley T. The rmeta Package, Version 2.14, 2008).

4. RESULTS

Table 2 Summary of pooled data comparing LIHR and OIHR

Outcome Variables	Pooled OR or WMD	Test for Overall Effect		Test for heterogeneity	
		Z	ρ	χ^2	ρ
Operating times	14.08(8.36, 19.80)†	4.83	<0.0001	8830.741	<-0.0001
Hospital stay	-0.06(-0.19,0.08)†	-0.80	0.4223	4261.20	<0.0001
Return to normal	-4.99(-6.1,3.88)†	-8.81	<0.0001	669.16	<0.0001
Return to work	-6.39(-7.95,4.84)†	-8.06	<0.0001	597.95	<0.0001
Complication	0.66(0.53,0.82)*	-3.78	0.0002	186.56	<0.0001
Recurrence	1.19(0.92,1.56)*	1.32	0.1874	82.90	0.0031

Values in parentheses are 95 percent confidence intervals. * stands for OR odds ratio; † stands for WMD weighted mean difference.

For three of the six outcomes (see table 2) the summary point estimates favoured LIHR over OIHR; there was a significant reduction of 34 percent in the relative odds of postoperative complications OR 0.66, 95% confidence interval (CI) 0.53 to 0.82; $P = 0.0002$), 4.99 (WMD -4.99, 95% CI -6.10 to -3.88; $P < 0.0001$) days in time to return to normal activity and 6.39 (WMD -6.39, 95% CI -7.95 to - 4.84; $P < 0.0001$) days in time to return to work. There was a significant increase of 14.08 (WMD 14.08, 95% CI 8.36 to 19.80; $P < 0.0001$) min in the mean operating time for LIHR. The relative odds of short term recurrence were increased by 20 percent for LIHR compared with OIHR (OR 1.19, 95% CI 0.92 to 1.56; $P = 0.1874$) and a reduction of 0.06 days of duration of hospital stay (WMD -0.06, 95% CI -0.19 to 0.08; $P = 0.4223$) for LIHR compared with OIHR, although these results were not statistically significant.

5. DISCUSSION

Laparoscopic surgery continues to be a rapidly advancing and pioneering field. Many different procedures are now being performed laparoscopically, primarily due to the perceived, and in some cases (i.e. laparoscopic cholecystectomy) confirmed benefits of minimally invasive surgery. LIHR has been controversial since its introduction in the early 1990s (Memon and Fitzgibbons, 1998; Memon et al., 1997). Those supporting LIHR claim reduced post-operative pain, earlier return to work or full physical activity and superior cosmesis when compared to OIHR (Felix and Michas, 1993; Filipi et al., 1992; Fitzgibbons et al., 1994; Ger et al., 1993; Mckernan and Laws, 1993). Critics of LIHR have cited increased operating time, as well as cost and the associated technical difficulties of the procedure (Memon and Fitzgibbons, 1998).

Operating time in the data analysed was shown to be significantly reduced in the OIHR group versus the LIHR procedures by 14 minutes. This is not surprising considering the extra time required in preparing equipment and gaining access to the operative area. Surgeon experience also has a marked effect on the time taken per operation, with later trials displaying laparoscopic operating time very similar to the open procedure. It has been estimated that LIHR increased theatre cost by around $600 (US), moreover the effect of longer operating time on the patient may increase morbidity and mortality (Memon et al., 2003; Voyles et al., 2002).

Duration of hospital stay, a frequently sited benefit of laparoscopic surgery, was not significantly different between the two groups. This has been a variable of considerable dispute in the literature. Previous systematic reviews have come to differing results, either in favour of

LIHR or with no significant difference in hospital stay, as this review found. Importantly, no review has found that LIHR increases hospital stay versus OIHR, and in general the trend is toward decreased stay for LIHR (Kuhry et al., 2006; McCormack et al., 2003; Memon et al., 2003; Schmedt et al., 2004; Voyles et al., 2002). An explanation for this may be in the increasing proportion of inguinal hernia repairs done as day cases, reducing overall length of stay for OIHR patients and thus nullifying the statistically significant findings of early reviews with the addition of more recent RCTs (Aylin et al., 2005).

Return to normal activity clearly favoured LIHR (5 days) as did time to return to work (6.4 days), and of all the variables favouring LIHR, this has been a consistent finding (Kuhry et al., 2006; McCormack et al., 2003; Memon et al., 2003; Schmedt et al., 2004; Voyles et al., 2002). Factors influencing this finding obviously include the lack of a muscle disruption, no groin incision and reduced tissue manipulation. Further explanations of this difference between OIHR and LIHR centre on so-call physician and/or patient bias, but this is very difficult to quantify. Odds ratio of overall complications significantly favoured the LIHR group. This finding is consistent with our previous meta-analysis, and other earlier systematic reviews (McCormack et al., 2003; Memon et al., 2003; Schmedt et al., 2004; Voyles et al., 2002). Further sub-group analysis in this area is pending as it has been suggested that LIHR is associated with rare but severe complications such as major vascular injury and bowel perforation; this was not supported by our earlier study (Kuhry et al., 2006; Memon et al., 2003).

Overall recurrence favours OIHR over LIHR, (OR 1.19) however this is not significant (see table 2). LIHR has been shown to be superior than the sutured/tension varieties of OIHR which are little used in current practice, however when a 'modern' non-tension mesh OIHR is performed there is no difference between the two in recurrence rates (Brooks, 2007; Memon et al., 2003). Of the two primary LIHR techniques commonly used, our analysis showed that the RCTs employing the Total Extraperitoneal (TEP) repair had a strong trend towards a decreased recurrence rate, the opposite was true for the RCTs employing the TAPP (Transabdominal Pre-Peritoneal) repair; neither reached statistical significance. This trend was not noted in previous meta-analyses, and the opposite for the TAPP repair has been previously noted (McCormack et al., 2003). Many more studies using the TEP method have been published since 2003, the first meta-analysis by Memon et al. (2003) included 22 RCTs reporting TAPP versus OIHR and only 6 employing a TEP approach. This study included 34 RCTs purely comparing TAPP with OIHR and 20 comparing TEP with OIHR, the increase in trials reporting a TEP approach may somewhat explain this change in trend. Long-term follow-up is crucial to meaningful estimation of recurrence, with most recurrences occurring between 5 to 10 years post herniorrhaphy; studies reporting long-term recurrence rates with LIHR are eagerly awaited (Memon et al., 2003).

6. CONCLUSIONS

LIHR is an exciting development in the continuing evolution of general surgery. This meta-analysis both confirms results from previous reviews, but raises some new questions. Operation time for LIHR exceeds that its open counterpart, while return to work and normal activity are dramatically reduced, furthermore the complication rate associated with LIHR is comparable with that of OIHR. While these variables are consistent with previous analyses published, our data suggests a trend to increased recurrence with the TAPP LIHR as compared to OIHR, with the opposite finding for TEP versus OIHR; further sub-group analysis is pending. Long-term recurrence rates are still required however to make a definitive judgement in this area.

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