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ORIGINAL CONTRIBUTIONS

A Cadaveric Porcine Model for Assessment in Laparoscopic Bariatric Surgery—a Validation Study

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Abstract
Background Laparoscopic Roux-en-Y gastric bypass (LRYGBP) is the most effective surgical therapy for morbid obesity. It is an advanced laparoscopic surgical procedure and has a protracted learning curve. Therefore, it is important to develop innovative ways of training and assessing surgeons. The aim of this study is to determine if a cadaveric porcine jejuno-jejunostomy model is an accurate way of assessing a surgeon's technical skills by determining if a correlation exists with how he performs in the operating room.
Methods Eight surgeons of varying experience performed a side-to-side stapled jejuno-jejunostomy on a cadaveric bench model before proceeding to perform the procedure on a real patient scheduled for LRYGBP. Performance was assessed using a motion tracking device, the Imperial College Surgical Assessment Device. Each procedure was recorded in video and scored by two blinded expert surgeons using procedure-specific rating scales.
Results The cadaveric bench model demonstrated concurrent validity with significant correlations between performance on the cadaveric model and patient for dexterity measures. Left-hand path length, r=0.857 (median, 27, 41.3; P=0.007), right-hand path length, r=0.810 (median, 31.5, 60; P=0.015) and total number of movements, r=0.743 (median, 422, 637; P=0.035). This correlation in performance was also demonstrated in the video rating scales, r=0.727 (median, 13.2, 14.8; P=0.041). No correlation was found in operative time (median, 541, 742; P=0.071).
Conclusions This study demonstrates the concurrent validity of the cadaveric porcine model, showing similar performances in surgeons completing a jejuno-jejunostomy on the cadaveric model and the patient.

Keywords Simulation · Gastric bypass · Laparoscopy · Bariatric surgery · Education · Surgery · Training/courses

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Introduction

Roux-en-Y gastric bypass (RYGBP) has been well documented as a reliable procedure for the surgical treatment of morbid obesity [1]. Many randomised trials have declared RYGBP to be the procedure of choice [2–4]. It has been shown that Laparoscopic RYGBP (LRYGBP) is more beneficial to patients in terms of decreased postoperative pain, earlier mobilisation, shorter hospital stay and shorter sick leave [4]. There have been many studies and reviews published that demonstrate extensive benefits with better outcomes when a laparoscopic approach is used [5–9]. The most commonly performed bariatric procedures are laparoscopic adjustable gastric banding (LAGB) and LRYGBP [10]. LABG is the most frequently performed bariatric procedure in Europe with LRYGBP being more common in the USA, where it is now considered the gold standard procedure for bariatric surgery [10–12].

The traditional method of training surgeons to perform LRYGBP is the apprenticeship model. This involves allowing the inexperienced surgeon to operate on live patients under supervision [13]. Understandably, this will lead to errors and complications that may have been prevented with an experienced primary surgeon [14]. In the USA, fellowships are a commonly used method for augmenting technical skills and surgical experience, allowing post-residency surgeons to reduce their learning curve. There are over 100 available fellowship programmes in the USA for bariatric surgery but are highly competitive. Also, many surgeons enter fellowships with little or no advanced laparoscopic skills and may have higher complication and failure rates [5, 15–17].

Due to the inherent risk that is associated with procedural learning curves, there has been increased interest by surgical societies and industry in training advanced laparoscopic techniques outside of the operating room. This has led to the development of animate and inanimate training models that allow surgeons to shorten the learning curve and reduce complication rates before operating on real patients [18]. Aggarwal et al. [5] have developed a training and assessment tool for LRYGP. This involved the creation of a cadaveric porcine assessment tool that allows surgeons in training to perform a simulated side-to-side laparoscopic jejuno-jejunostomy. The cadaveric model is a standardised and reproducible assessment modality that provides assessment of both manual dexterity and quality of performance. The cadaveric porcine jejuno-jejunostomy model has been validated for face validity (i.e. it is realistic) and construct validity (i.e. it is able to determine surgical experience, done by comparing the performance of inexperienced and experts on the model) as a training and assessment tool [5]. Validation of this assessment tool implies that it can be reliably used to accurately measure technical skills for cohorts of surgeons in training. It is a realistic simulator that will be able to distinguish between surgeons of different levels. Even though it has been used as the core of new advanced laparoscopy training programmes [19], it has yet to demonstrate its usefulness in performing the same procedure in the operating room. For this model to be widely adopted as a training and assessment tool for surgeons, it is vital to show that performing the procedure well on the model implies that you will perform the procedure well in the operating room. Concurrent validity of a simulator is determined by demonstrating that there is a correlation between performance on the simulated model and in the operating room, which is the gold standard for teaching this procedure [20]. The aim of this study is to establish the concurrent validity of the cadaveric porcine jejuno-jejunostomy bench model as an assessment tool.

Materials and Methods

Subjects

Eight surgeons from a bariatric surgical training programme were recruited. The participants had varying laparoscopic bariatric experience (numbers of LRYGBP: median 38; range 0–340). Each surgeon was asked to perform a laparoscopic jejuno-jejunostomy in a box trainer. This was followed by performing the jejuno-jejunostomy stage of a LRYGBP in a real patient in the operating room. Afterwards, a comparison was made between the performances in the bench model vs that in the operating room in order to find out if a correlation existed. The study was explained to all participants prior to enrolment, and informed consent was obtained.

Cadaveric Porcine Model

The cadaveric porcine jejuno-jejunostomy bench model was set up using the protocol given by Aggarwal et al. [5] A sample of cadaveric porcine small bowel was harvested from one animal. It was divided into 50 cm sections and placed into a box trainer. The bowel segments were fixed by their mesentery to a cork board using a heavy-duty stapler and positioned in a U-shape. The sample of small bowel was then filled with thickened fluid to replicate live tissue. This model provides a simulation of two sections of small bowel lying adjacent to each other. Each subject was then asked to perform a laparoscopic jejuno-jejunostomy. Each procedure involved the placement of an intracorporeal stay suture, followed by making two enterotomies using either diathermy or harmonic scalpel. A laparoscopic linear stapler was positioned between the two limbs of the bowel before firing. Finally, the enterotomy was closed using a laparoscopic running suture technique.

Patient Jejuno-jejunostomy

Following completion of the cadaveric bench model, each participant performed the jejuno-jejunostomy stage of a LRYGBP on a real patient scheduled for the procedure on an elective list. Each surgeon was either supervised by the consultant surgeon as per the usual apprenticeship guidelines or the subject was the consultant surgeon in charge of the operating list. Patients were informed beforehand, and consent was obtained to record the procedures.

After informed consent was obtained, tracking sensors were attached to the dorsum of each surgeon's hands under sterile gloves. Surgery was performed with the patient in supine position, using a 5 trocar technique with the surgeon standing to the right of the patient. After induction of anaesthesia and antibiotic prophylaxis, the abdominal cavity was accessed using an optical trocar (ENDOPATH Xcel Bladeless trocar, Ethicon Endosurgery, Cincinnati, OH, USA). Carbon dioxide pneumoperitoneum was maintained up to 15 mmHg pressure. All trocars were inserted under direct vision. The jejuno-jejunostomy was performed 30 cm from the angle of treitz. The transection of the jejunum was done using a 45-mm endoscopic stapler (Endopath ETS45, Ethicon Endosurgery, Cincinnati, OH, USA) and white cartridge, and a 150-cm alimentary limb was created after dissecting the meso with the harmonic scalpel. A traction stitch was then placed using absorbable sutures, and an enterotomy was performed on each segment of the bowel using the harmonic scalpel. The stapler was introduced on both enterotomies and fired. The defect was closed using vicryl 3.0.

Assessment Tools

The performances in the skills laboratory and the operating room were assessed in an identical manner. Manual dexterity was measured using the Imperial College Surgical Assessment Device (ICSAD) motion tracking device. This involved attaching tracking sensors on the dorsum of each hand. The time taken, number of hand movements and path length of each hand (i.e. how far each hand moves) could then be measured whilst the procedures were carried out. ICSAD has been widely validated as an accurate motion tracking device for measuring surgical dexterity [21]. The ICSAD software can synchronously record the videos of the performances from the laparoscopic stack. Quality of performance was assessed by post-hoc analysis and rating of the videos by two blinded experienced surgeons. We used procedure-specific rating scales that have been previously validated as an assessment tool for laparoscopic jejuno-jejunostomy [5]. The rating scale has four areas of marking, each with a score of 1 to 5, with a total score of 20.

Statistical Analysis

Data were analysed with the Statistical Package for Social Science version 11.5 (SPSS, Chicago, IL, USA) using parametric and non-parametric tests. A P value <0.05 was considered as statistically significant.

Results

The results of this study demonstrate the feasibility of using the cadaveric porcine jejuno-jejunostomy model as an assessment tool. There are significant correlations for all eight surgeons in performance in the skills lab with their performance in the operating room.

Analysis of dexterity demonstrated a correlation for the number of hand movements with a median number of 422 (± 110) on the bench model and 637 (± 281) on the patient, r= 0.743 (Fig. 1). This had a statistical significance with median P=0.035. There was a correlation in path length for both the left and right hand between the patient and bench model with left-hand path length, r=0.857 (median, 27, 41.3; P=0.007) and right-hand path length, r=0.810 (median, 31.5, 60; P= 0.015) (Fig. 2). However, the only parameter that did not show a significant correlation was for time taken to complete the procedure, r=0.667 (median, 541, 742, P=0.071) (Fig. 3).

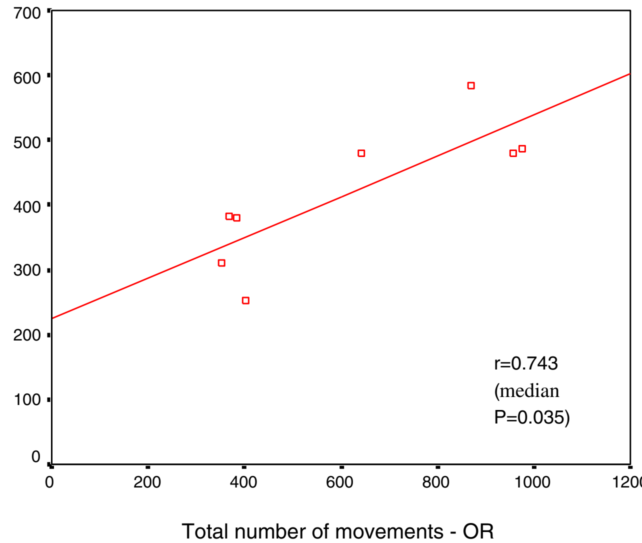

Fig. 1 Univariable regression to illustrate the number of movements performed on the bench model and in the patient

Analysis of quality of performance also demonstrated a significant correlation (r=0.727) between performance on the box trainer and performance in the operating room. The procedure-specific rating scales showed a median score of 13.2 for the box trainer and 14.8 for performance in the operating room. This was statistically significant (median P=0.041) (Fig. 4).

Discussion

Over the past few years, there has been increased interest in improving the training of advanced surgical techniques. Reduced working hours, a drive to have efficient operating lists, improved patient safety and a consultant-led service have all had an effect in reducing the training opportunities for surgical apprentices. It is now unacceptable and inappropriate to practice surgical techniques at any level on patients even if they give their prior consent. It is vital that we develop new ways of teaching advanced surgical techniques by shifting training from the operating room and into the skills lab [22].

This study has demonstrated an interesting area of surgical training and assessment. Most surgical training programmes assess surgeons through yearly evaluations by the master surgeon. These may be biased, subjective and cannot demonstrate consistency between surgeons [23]. This study has demonstrated a novel way to assess a surgeon's technical skills such that it correlates with their operating room performance. Knowing that experts behave competently in both the laboratory and in the operating room establishes a cutting point in technical skills for

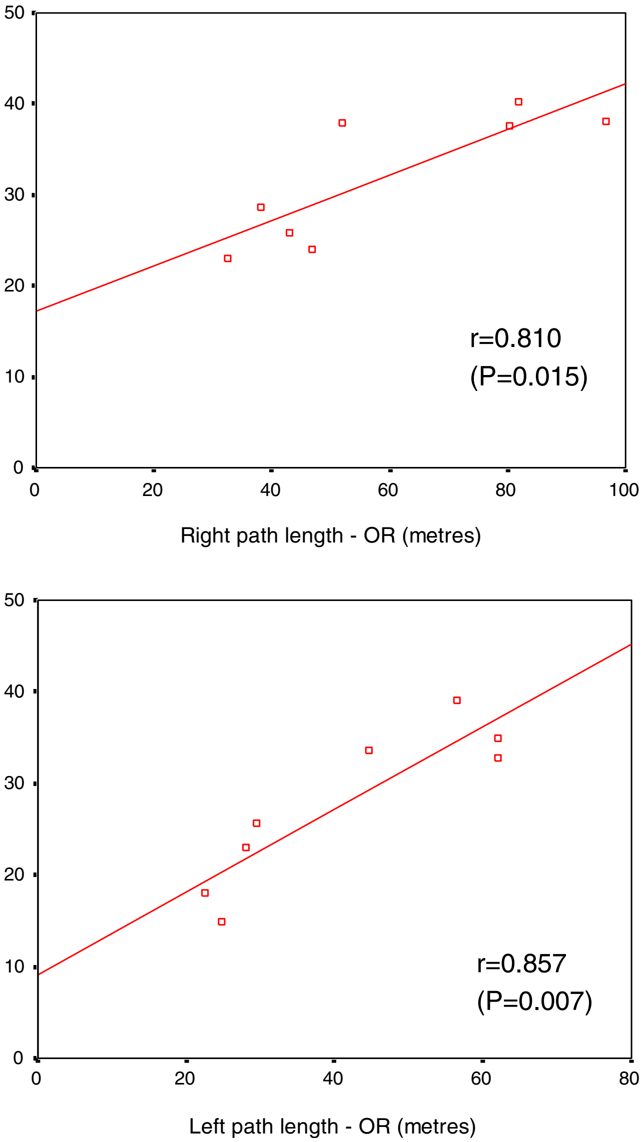

Fig. 2 Univariable regression to illustrate the video rating scales on the bench model and in the patient

trainees to achieve. Novices will now need to train in the lab until competency is obtained. This competency parameter is based on the performance of experts in the laboratory.

The only parameter that did not show a significant correlation was the time taken to complete the procedure. Although a positive correlation tendency was observed (r= 0.667), this was not significant perhaps because of the low number of surgeons recruited in our study. However, even obtaining a significant correlation in the operating time, the importance of performing a procedure correctly overcomes the need to execute it in a given time.

The cadaveric porcine jejuno-jejunostomy model has previously been shown to have face (i.e. it is realistic) and construct validity (i.e. it can differentiate between surgeons of differing ability and experience) [5]. This study has

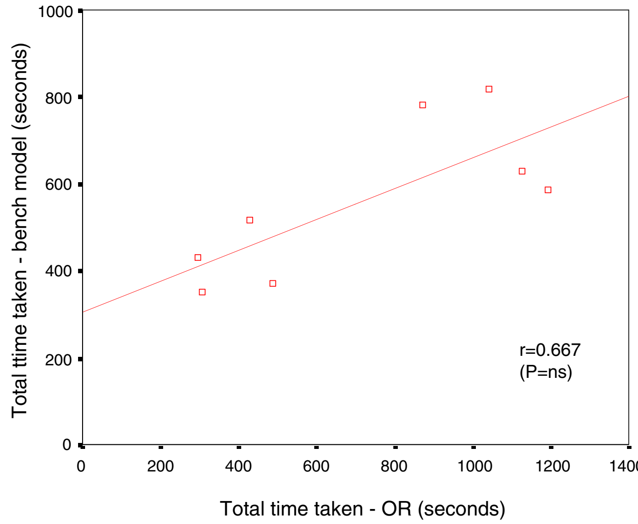

Fig. 3 Univariable regression to illustrate the total path length (metres) required to complete a jejuno-jejunostomy on the bench model and in the patient

clearly shown concurrent validity, implying that a surgeon's performance in the operating room will correlate with their performance on the model. This is an extremely important finding. The model could be used for assessment of surgeons of all levels as it provides a unique way of objectively and consistently assessing surgeons' technical skills.

The work in this study with the cadaveric model was primarily to investigate the feasibility of an assessment tool in the wider context of a structured curriculum for LRYGBP. Technical skills training for any procedure or operation may follow a structured framework, with completion demonstrated by attainment of proficiency. The cadaveric porcine model in this study has been validated as a proficiency-based technical skills

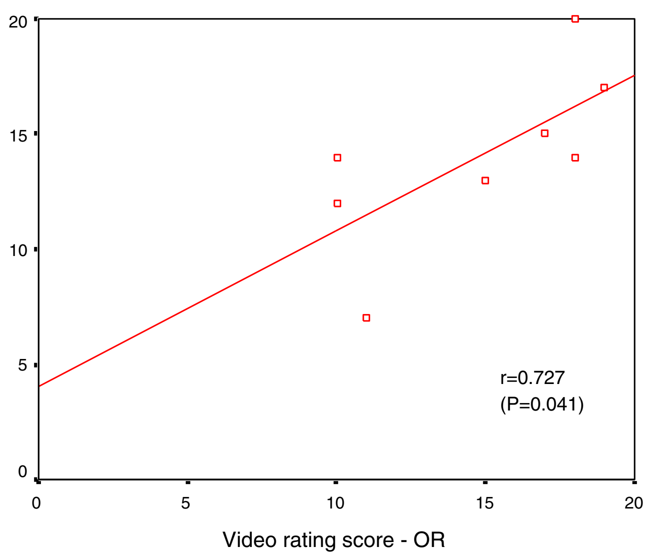

Fig. 4 Univariable regression to illustrate the total time taken to complete the task on the bench model and in the patient

assessment tool and therefore is ideally suited to be used within a structured curriculum for LRYGBP. This curriculum could follow documented technical skills frameworks that involve the defragmentation of a full operation or procedure, allowing a surgeon to train and obtain proficiency in each fragment prior to attempting the full-length procedure [24]. The cadaveric porcine model provides a validated, proficiency-based assessment for the jejuno-jejunostomy part of a LRYGBP.

Furthermore, the development of a validated technical skills assessment tool for advanced laparoscopic surgery has many applications. Traditionally, entry to a national laparoscopic training programme has relied on the interview process for assessment of surgical competence. Recently, however, policy-makers and governing bodies have taken an interest in the selection process for training programmes and re-certification. Interviews can be subjective, are not standardised and cannot be uniformly consistent and fair to all candidates. This study provides a technical skills station that could improve the selection processes by consistently assessing a surgeon's advanced technical skills which can accurately correlate with their performance in the operating room. This is also relevant for re-certification as it would be an invaluable way of quickly and efficiently assessing a senior surgeon's ability to continue to perform complex procedures.

The cadaveric porcine model assessed in this study can be accurately used by surgical training programmes as a fully validated surgical assessment tool for skills that are required for advanced laparoscopic surgery. The model is cheap, mobile and easily reproducible for any surgical training programme. It also does not have the ethical and cost-effective dilemmas associated with live porcine models or the costs of synthetic or virtual reality simulators. Further work in this area should be on the development of validated surgical assessment tools for other specialities and their incorporation into structured training programmes.

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Conflict of Interest The authors report no conflict of interest. The authors are responsible for the content and writing of the article.

References

1. Fobi MA, Lee H, Holness R, et al. Gastric bypass operation for obesity. World J Surg. 1998;22(9):925–35.
2. Olbers T, Fagevik-Olsen M, Maleckas A, et al. Randomized clinical trial of laparoscopic Roux-en-Y gastric bypass versus laparoscopic vertical banded gastroplasty for obesity. Br J Surg. 2005;92(5):557–62.
3. Sugerman HJ, Starkey JV, Birkenhauer R. A randomized prospective trial of gastric bypass versus vertical banded gastroplasty for morbid obesity and their effects on sweets versus non-sweets eaters. Ann Surg. 1987;205(6):613–24.
4. Westling A, Gustavsson S. Laparoscopic vs open Roux-en-Y gastric bypass: a prospective, randomized trial. Obes Surg. 2001;11(3):284–92.
5. Aggarwal R, Boza C, Hance J, et al. Skills acquisition for laparoscopic gastric bypass in the training laboratory: an innovative approach. Obes Surg. 2007;17(1):19–27.
6. Nguyen NT, Ho HS, Palmer LS, et al. A comparison study of laparoscopic versus open gastric bypass for morbid obesity. J Am Coll Surg. 2000;191(2):149–55. discussion 155–7.
7. Nguyen NT, Goldman C, Rosenquist CJ, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. Ann Surg. 2001;234(3):279–89. discussion 289–91.
8. Nguyen NT, Lee SL, Goldman C, et al. Comparison of pulmonary function and postoperative pain after laparoscopic versus open gastric bypass: a randomized trial. J Am Coll Surg. 2001;192(4):469–76. discussion 476–7.
9. Nguyen NT, Hinojosa M, Fayad C, et al. Use and outcomes of laparoscopic versus open gastric bypass at academic medical centers. J Am Coll Surg. 2007;205(2):248–55.
10. Tice JA, Karliner L, Walsh J, et al. Gastric banding or bypass? A systematic review comparing the two most popular bariatric procedures. Am J Med. 2008;121(10):885–93.
11. Buchwald H, Williams SE. Bariatric surgery worldwide 2003. Obes Surg. 2004;14(9):1157–64.
12. Santry HP, Gillen DL, Lauderdale DS. Trends in bariatric surgical procedures. JAMA. 2005;294(15):1909–17.
13. Pellegrini CA, Warshaw AL, Debas HT. Residency training in surgery in the 21st century: a new paradigm. Surgery. 2004;136(5):953–65.
14. Schauer P, Ikramuddin S, Hamad G, et al. The learning curve for laparoscopic Roux-en-Y gastric bypass is 100 cases. Surg Endosc. 2003;17(2):212–5.
15. Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Integrating advanced laparoscopy into surgical residency training. Surg Endosc. 1998;12(4):374–6.
16. Society of American Gastrointestinal Endoscopic Surgeons (SAGES) and the SAGES Bariatric Task Force. Guidelines for institutions granting bariatric privileges utilizing laparoscopic techniques. Surg Endosc. 2003;17(12):2037–40.
17. Rattner DW, Apelgren KN, Eubanks WS. The need for training opportunities in advanced laparoscopic surgery. Surg Endosc. 2001;15(10):1066–70.
18. Jackson CR, Gibbin KP. 'Per ardua…' Training tomorrow's surgeons using inter alia lessons from aviation. J R Soc Med. 2006;99(11):554–8.
19. Vara J, Mejía R, Riquelme A et al. Significant transfer of surgical skills obtained with an advanced laparoscopic training program to a laparoscopic jejunojejunostomy in a live porcine model: feasibility of learning advanced laparoscopy in a general surgery residency. Surg Endosc. 2012:1–9.
20. McDougall EM, Corica FA, Boker JR, et al. Construct validity testing of a laparoscopic surgical simulator. J Am Coll Surg. 2006;202(5):779–87.
21. Datta V, Mackay S, Mandalia M, et al. The use of electromagnetic motion tracking analysis to objectively measure open surgical skill in the laboratory-based model. J Am Coll Surg. 2001;193(5):479–85.
22. Aggarwal R, Darzi A. Technical-skills training in the 21st century. N Engl J Med. 2006;355(25):2695–6.
23. Cuschieri A, Francis N, Crosby J, et al. What do master surgeons think of surgical competence and revalidation? Am J Surg. 2001;182(2):110–6.
24. Aggarwal R, Grantcharov TP, Darzi A. Framework for systematic training and assessment of technical skills. J Am Coll Surg. 2007;204(4):697–705.