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A novel model for hands-on laparoscopic pelvic surgery training on Genelyn-embalmed Body Donors: an initial feasibility study.

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Abstract

Objectives: Human body donors are a well-accepted *ex vivo* model for laparoscopic surgical training. Unembalmed, or fresh frozen, body donors are high fidelity models. However, their short life-span and high cost relatively limit the hands-on training benefits. In contrast, soft embalmed body donors have a relatively longer usability without compromising tissue flexibility. This study reports the initial experience of the utility and feasibility of Genelyn-embalmed body donors as a novel soft-embalmed cadaveric model for laparoscopic surgical training.

Method: An expert laparoscopic surgeon, who organised many fresh frozen body donor courses, performed deep laparoscopic pelvic dissection and laparoscopic surgical tasks including suturing and electrosurgery on a single Genelyn-embalmed body donor. The three sessions were performed over a course of three weeks. The donor was fully embalmed using the Genelyn technique. The technique consisted of a single point closed arterial perfusion of embalming solution via the carotid artery with no further exposure to or immersion in embalming fluids thereafter.

Results: The Genelyn-embalmed donor provided a feasible model for laparoscopic surgical training. Initial experience shows evidence of this model having being feasible and realistic. There was reproducibility of these qualities across a minimum of three weeks in this single donor study.

Conclusions: The initial experience shows that Genelyn-embalmed body donors provide a novel model for laparoscopic surgical training which possesses fidelity and is feasible for laparoscopic training. While there needs to be further studies to validate these findings, this technical note provides perspectives from an expert trainer regarding this model and provides a photographic and videographic atlas of this model's use in laparoscopy.

Introduction

Laparoscopic surgery is now commonplace in surgical practice across a wide breadth of specialties including abdominal surgery, urology and gynaecology (Piechaud and Pansodoro, 2006; Pattanshetti and Pattanshetti, 2010; Stovall et al, 2006; Zevin et al, 2012). There is good evidence that laparoscopic surgery is associated with improved patient outcomes such as shorter recovery times and reduced need for analgesia (Pattanshetti and Pattanshetti, 2010). These together with other benefits of laparoscopic surgery, such as reduced hospital stay and optimal resource-usage, lead to higher cost-effectiveness in a variety of pathology treated with laparoscopic procedures (Mar et al, 2018; Bijen et al, 2011; McCormack et al, 2005). The popularity of laparoscopic surgical techniques is increasing. Nevertheless, it is well recognised that laparoscopic surgical techniques involve a longer learning curve than with open surgical techniques (Miskovic D et al, 2010; Samia et al, 2013; Emken et l, 2004).

Current trends suggest a move from the traditional apprenticeship model, centered in the operating theatre, to more structured training modalities using *ex vivo* models i.e. not involving real patients (Aggarwal and Darzi, 2005). This has been motivated by factors such as the aforementioned steeper learning curve in laparoscopic surgery skills acquisition, as well as time pressures caused by reduced availability of training hours to surgical trainees (Samia et al, 2013; Aggarwal and Darzi, 2005). There are concerns that these factors may be associated with poorer clinical and safety outcomes in patients undergoing these procedures (Samia et al, 2013).

This has driven the development variety of *ex vivo* models to train novice and expert surgeons alike in laparoscopic surgery (Pattanshetti and Pattanshetti, 2010; Samia et al, 2013). These include body donor models, live anaesthetised animal models, bench models and virtual reality trainers. A variety of factors have to be considered in selecting a model for surgical training and these include costs, fidelity, relative cost effectiveness and availability (Pattanshetti and Pattanshetti, 2010).

Body donor models are very high fidelity models amongst a wide range of available *ex vivo* models (Reddy et al, 2017; Andrews et al, 1995; Munshi et al, 2015; Stefanidis et al, 2013; Wyles et al, 2011). The traditional body donor model for use in surgical training, the unembalmed or fresh frozen body donor, has reported disadvantages such as a short life-span, need for refrigeration, cost and odour (Eisma and Wilkinson, 2014; Jaung et al, 2011). Traditional embalmed body donors using high formalin concentrations have limited use in surgical training due to poor tissue flexibility but excellent structural preservation (Lloyd et al, 2011; Reddy et al, 2017).

Soft embalmed body donors in contrast are characterised as a cadaveric model which allows for both adequate tissue flexibility and an acceptable lifespan (Eisma and Wilkinson, 2014; Lloyd et al, 2011). Currently available soft embalming techniques use a variety of different chemical tissue fixation formulation, each conferring different physico-mechanical properties to the body donor (Jaung et al, 2011; Reddy et al, 2017).

The Genelyn embalming technique employs a proprietary arterial embalming solution developed by a company based in Australia. Its exact chemical composition has not been revealed by the manufacturer but material its material safety data sheet lists formaldehyde, ethanol and 1-methoxy-2-propanol as its main constituents (Lloyd et al, 2011; EEPCO Ltd, 2018).

There, however, remains no consensus on the most effective and sustainable model for laparoscopic surgical skills training, despite a growing importance to have such a model.

In this feasibility study, an expert laparoscopic surgeon and trainer undertook a dissection of the pelvic side wall structures and some basic and general laparoscopic surgical tasks including suturing and electrosurgery on a Genelyn-embalmed body donor over a course of three weeks, with the aim of documenting the fidelity and face validity of this modality.

Method:

Embalming Technique

Donors were fully embalmed using Genelyn (Anatomical Series, Genelyn, Australia), a proprietary embalming solution. The exact constituents are unknown due to its proprietary nature but there is publicly available data on certain constituents of the mix in its material data safety sheets. These report a relatively low formadehyde concentration (1.85% m/m) (EEPCO Ltd, 2018). Other main reported constitutents of the solution are ethanol and 1-methoxy-2-propanol (EEPCO Ltd, 2018). The fluid was introduced to the body donor via single-point perfusion, using a pump to gently convey 20-30L of fluid into the donor via the right carotid artery over a period of 2-4 hours. The volume required was pragmatically determined dependent on donor size. This was done within 48-72 hours of death. Once complete, the incision point for infusion was closed and the donor placed in refrigerated storage for at least three months, the optimal time required to let the fluid fully perfuse the tissue and cure. At completion of this period the donor was brought to the Dissection Room where storage and maintenance were simply to keep the donor covered with non-transparent plastic (or a clear plastic sheet covered with a non-plastic, non-transparent sheet) and to spray with a hydrating solution whenever the sheets were removed. No further exposure to embalming fluids was required, nor were the donors immersed in any fluid at any time.

Cadaveric Dissection

An expert laparoscopic surgeon undertook laparoscopic pelvic dissection on a single Genelyn-embalmed male body donor over a course of three dissection sessions across three weeks. The novice laparoscopic surgeon undertook the role of assistant and laparoscopic camera holder.

The body donor was positioned in the Trendelenburg position (“head-down”). Skin incisions (1mm in length) were made at four sites corresponding to the port insertion sites: a single 5 mm screw port intra-umbilically (terminium port, Karl Storz), two 5 mm screw ports inserted 2 cm lateral and above the left and right anterior superior iliac spines, and a balloon port 8 cm in the midline below the umbilicus. Pneumoperitoneum was induced and maintained with gas flow 15 L/min and air pressure of 25 mmHg (Figure 1).

Dissections of the retropubic space of Retzius and pelvic side-walls were performed. A few key anatomical structures were dissected and skeletanised: 1) left and right obturator vessels entering the obturator canal, 2) the spermatic cord entering the inguinal canal and 3) the right ureter traversing into the pelvis and entering the bladder after passing through the ureteric tunnel.

Intracorporeal and extracorporeal suturing of the parietal peritoneum, bladder and pectineal ligament was performed. Electrosurgical techniques were performed on peritoneum as well, including monopolar diathermy, bipolar diathermy and bipolar coagulation (Ligasure, Covidien).

Subjective descriptive assessments of the following factors were made on the face validity of the donor by the expert laparoscopic surgeon: 1) Ability to maintain pneumoperitoneum 2) Surgical anatomy , 3) Tissue colour, consistency, odour, tissue handling and ease of dissection, 4) The use of instruments, sutures and electrosurgery on tissues. Where possible and relevant, comparisons were made between these factors at the 1st session and subsequent sessions. These assessments were considered in terms of simulation fidelity, specifically considering physical, functional and psychological fidelity

(16-17).

Ethics approval

The study was given ethical approval by the Lead Licensed Teacher in Human Anatomy at the University of Glasgow in accordance with the Human Anatomy Act (Scotland) (2006).

Results

Pneumoperitoneum

Pneumoperitoneum was successful with gas flow 15 L/min and air pressure maintained at 25 mmHg (Figure 1). This was maintained across the three weeks.

Surgical Anatomy

The anatomy was indistinguishable from in vivo models. Specific examples of surgically relevant anatomy were demonstrated through the laparoscopic dissections including corona mortis, obturator vessels, inferior epigastric vessels, external iliac vessels, spermatic cord, and deep inguinal ring. (Figure 2).

Tissue Colour and Odour

Tissue colour was preserved and while not completely similar to *in vivo* settings was realistic (Figure 2). There was minimal bad odour as reported by the novice and expert laparoscopic surgeon throughout the sessions.

Tissue Handling and Dissection

The tactile feedback and consistency of tissues was very realistic providing good functional validity. Dissection was similar to *in vivo* in that pneumoperitoneum aided in dissection of the tissues. The bowel was of a harder consistency and it was more difficult to displace the bowel from the pelvis. However, the bowel generally did not spontaneously return to the intended operative site. Bowel clearance would have made this task easier and can be readily achieved in the laboratory setting. The use of bowel retractors however was of value. Video 1 and Video 2 provide evidence of effective laparoscopic dissection and tissue consistency.

Fluids and Suction

There was a minimal need for suction as there was comparatively less tissue fluid, and there was no need for suction throughout the sessions. The level of dependent fluid in the rectovesical pouch during the second dissection session (week 2) was low (Figure 3).

Vasculature

There was oozing of blood-coloured embalming fluid with the cutting of vascular structures in a manner that was considered realistic and similar to in vivo models (Figure 4).

Suturing and instrumentation

The consistency and ease of suturing and laparoscopic instrumentation was very similar to operating on a live patient (Figure 5).

Electrosurgery

The lateral thermal spread and effect of electrosurgical instruments to tissues tested, which included monopolar diathermy and bipolar diathermy was similar to *in vivo* thermal spread.

Video 3 and Video 4 show the successful use of monopolar and bipolar devices.

Longevity

There was no perceived difference between all the aforementioned factors throughout the three sessions across a period of three weeks (Figures 6 and 7).

Discussion:

The current literature on the use of body donors in laparoscopic surgery shows that there is ample evidence for excellent physical validity, especially in terms of anatomical reproduction (Stefanidis et al, 2013; Wyles et al, 2011; Giger et al, 2008; Leblanc et al, 2010a; Leblanc et al, 2010b).

There, nevertheless, remains a paucity of high-quality studies which compare the objective efficacy and cost benefit analyses of body donors relative to the other *ex vivo* models such as animal models, box simulators and virtual reality, and also between unembalmed/fresh frozen and embalmed body donors in laparoscopic surgical training at any particular stage of the learning curve. The current literature focuses on trainee perceptions about the different models.

The paucity in evidence extends to comparisons between different body donor embalming techniques. This is likely driven by the popular use of the Thiel embalming technique which the most commonly reported soft embalming technique in body donor training models (Kerckaert, 2008; Eisma et al, 2013; Healy et al, 2015).

There is still limited literature reporting the use of Genelyn-embalmed body donors in the context of laparoscopic surgery. Rajasekhar et al (2021) report the experiences and perceptions of participants in a single laparoscopic surgical workshop using Genelyn body donors. The majority of participants agreed that the appearance and tactile fidelity of these body donors were similar to that of a live patient (Rajasekhar et al, 2021). The current study showed that the use of Genelyn-embalmed body donors is feasible in laparoscopic surgical training with very high physical and functional validity, displaying realistic anatomy and tissue colour, and allowing in vivo like dissection, tissue response and use of electrosurgery.

The current findings challenge those of Jaung *et al (2011)* which reported that Genelyn-embalmed tissues were indistensible although they did not test these tissues in a procedural or laparoscopic setting, limited their studies to anatomical joints and did not provide precise details of how the fluid was used.

As suggested by Rajasekhar et al (2021), these differences may be explained by the use of different Genelyn solution formulations/dilution protocols and infusion technique and methodology.

In terms of cost-effectiveness, there is evidence that soft embalmed body donors, have the added advantage of superior longevity, with potential for reduced costs with coordinated and sequential use when compared to fresh frozen models. The current cost for the Genelyn solution (Anatomical series) varies by supplier and geographical location due to its proprietary nature but the current publicly available cost for this specific formulation in

Europe sufficient for a single body donor is about £100-150 (EEPCo Ltd, 2022). This is supported by Rajasekhar et al (2021) who report that integrated costings from Genelyn embalming was lower compared to Thiel embalming. Blaschko *et al (2007)* showed that, while human body donor models were more expensive compared to animal and virtual reality models, the costs of these models could be reduced with planned, coordinated use by multiple specialties.

There are conflicting reports as to the longevity of the body donors embalmed in the Thiel technique. Kerckaert *et al (2008)* report that Thiel embalmed donors cannot be used for a prolonged period of time. This was in contrast with Eisma *et al* (2013) which reported feasible use of these donors across a period of three years, although use in laparoscopic surgical training were usually planned and reserved for the earlier periods in the donation timespan. Further, Eisma *et al (2013)* report the storage of the donor in Thiel embalming fluid between active use; different protocols in maintaining the embalmed donor may have given rise to these conflicting reports.

This continuous exposure to embalming technique makes the Thiel technique potentially a more complex technique logistically, requiring a significant increase in manual handling, high volumes of fluid and therefore less cost-effective compared to the Genelyn technique. A significant benefit in the model reported in the current study is that there is no necessity for repeated exposure to the embalming fluid; it is a potentially more cost-effective and reproducible than the Thiel technique. Further, there was no perceived deterioration in tissue quality over the three weeks of sequential use in this study. The repeated exposure to the embalming fluid in the Thiel technique may theoretically cause a higher risk of gradual loss of tissue flexibility across time, which is not a feature of Genelyn-embalmed donors (Blaschko *et al, 2007*).

Taken together, soft embalmed donors have a very important role to play in the current surgical training environment of reduced surgical training time in Europe, the United States of America (Samia et al, 2013; Healy et al, 2015) and elsewhere. Further, they provide an ethical and patient safety centered model of surgical training which departs from the dated ‘see one, do one, teach one’ adage (Rodriguez-paz et al, 2009). Training on body donors showed multiple benefits, namely high face validity and high perceived satisfaction with the model amongst trainees (Stefanidis et al, 2013; Wyles et al, 2011; Giger et al, 2008; Leblanc et al, 2010a; Leblanc et al, 2010b). The increased longevity and potential for sequential, coordinated use of Genelyn embalmed models for laparoscopic surgery may further allow increased uptake of this model due to increased cost-effectiveness.

The aim of this study is to present further data to the literature that Genelyn embalmed body donors are feasible as a model for laparoscopic surgical training and has face validity.

These findings from these exploratory feasibility study of one body donor needs to be validated with further studies with a focus on trainee and trainer perceptions of the utility, fidelity and validity of the model and formal cost-effectiveness evaluations.

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Figures

Figure 1: Successful induction and maintenance of pneumoperitoneum. Both panels show the insufflated peritoneal cavity. (a: median umbilical ligament)

Figure 2.1: Dissection of the anterior pelvis revealing the pelvic tubercle, corona mortis, obturator vessels and external iliac vessels. (a: pubic tubercle, b: right pubic ramus, c: external iliac vessels, d: *corona mortis*, e: obturator vessels traversing obturator foramen)

Figure 2.2: Skeletanisation of the ureter down to the vesicoureteric junction. (f: bladder (specifically at vesicoureteric junction), g: right ureter)

Figure 3: Appearance of dependent fluid in the rectovesical pouch.

Figure 4: Realistic extravasation of a vessel.

Figure 5.1 and 5.2: Successful placement of suture in the pectineal ligament (a: pubic tubercle b: pectineal ligament)

Figure 6.1 and 6.2: Non-deterioration of tissue appearances at subsequent dissection sessions across a period of three weeks (a: vas deferens). Top panel is from the first dissection session and bottom panel is from final dissection session.

Figure 7: Preserved omental tissue consistency in subsequent dissection session at week 3.

Videos

Video 1 and Video 2 shows realistic and successful tissue dissection in the pelvis.

Video 2 and Video 3 show successful use of monopolar and bipolar diathermy