Transabdominal pre-peritoneal (TAPP) vs totally extraperitoneal (TEP) laparoscopic techniques for inguinal hernia repair

An inguinal hernia (hernia in the groin) is a weakness in the wall of the abdominal cavity that is large enough to allow escape of soft body tissue or internal organ, especially a part of the intestine. It usually appears as a lump and for some people can cause pain and discomfort, limit daily activities and the ability to work. If the bowel strangulates or becomes obstructed it can become a life-threatening condition.

The direct costs of surgical hernia repair to the health service are large, as are indirect costs to employers and employed patients due to time off work following surgery. Hernia repair is one of the most common operations in general surgery with rates of repair ranging from 10 per 10,000 population in the United Kingdom to 28 per 10,000 in the United States (Chung 2007, Devlin 1995). Hernia repairs are responsible for approximately 80,000 finished consultant episodes, 100,000 bed days and 33,000 day cases per year in England and Wales alone (HES 2003). In the United States 700,000 patients seek treatment for hernia annually and a further 800,000 patients decline surgery (often claiming disability due to the presence of a hernia), accruing a total annual health care cost of over US$3 billion (Memon 1997, Stylopoulos 2002). An estimated total of 15 million working days are lost due to hernia in the United States each year (Memon 1998). Additionally, failures of surgical repair lead to increased patient discomfort, reoperations and further sick leave.

Surgical repair of inguinal hernia can be done under local or general anaesthesia. The surgery generally uses a synthetic mesh either with open surgery (using a conventional incision) or, increasingly, using less invasive procedures performed using a fibre optic laparoscope. Laparoscopic surgery is a minimal-access technique that allows the hernia repair to be undertaken without the need to open the abdominal wall. Patients undergoing laparoscopic inguinal hernia repair are often, but not always, treated as day cases.

The two most common laparoscopic techniques for inguinal hernia repair are transabdominal preperitoneal (TAPP) repair and totally extraperitoneal (TEP) repair. TAPP requires access to the peritoneal cavity with placement of a mesh through a peritoneal incision. The mesh is placed in the preperitoneal space covering all potential hernia sites in the inguinal region. The peritoneum is then closed above the mesh leaving it between the preperitoneal tissues and the abdominal wall where it becomes incorporated by fibrous tissue. TEP is different in that the peritoneal cavity is not entered and mesh is used to seal the hernia from outside the peritoneum. TEP is considered to be more technically difficult than TAPP but may lessen the risk of

damaging intra-abdominal organs and of adhesion formation leading to intestinal obstruction (which has been linked to TAPP), and it may save operative time as it is not necessary to incise and close the peritoneum from the inside. TEP is also thought to reduce post-operative pain.

The main health care resources used in primary laparoscopic inguinal hernia repair (amounts of resources may differ between TAPP and TEP) are: operative room time (duration); anaesthetic drugs (e.g. propofol or thiopental); post-operative inpatient hospital stay (duration); post-operative analgesics (e.g. paracetemol, non-steroidal anti-inflammatories, morfinomimetics); and post-operative follow-up outpatient visits (if medically indicated or requested by the patient). [Clue: There is no need to consider the costs (resource use) of laparoscopy equipment or mesh, since these costs (resource use) are the same for both experimental interventions (i.e. do not include either of these in the list of resources or resource/ cost inputs)].

Potential economic differences between TAPP and TEP which relate to clinical outcomes of the interventions include: time to return to usual activities (e.g. 'time to return to work' for employed patients) and resources used to manage sequelae and complications of treatment.

The main sequela of treatment using TAPP or TEP is hernia recurrence (recurrence of the original hernia). The main complications of treatment (serious adverse events) are vascular injury or visceral injury to intra-abdominal organs, which can be life-threatening. Less serious complications include: scrotal or trocar-site haematoma (clots); seroma (a mass or swelling caused by the localised accumulation of serum within a tissue or organ); wound/ superficial infection; mesh /deep infections; and port-site hernia (additional hernias developing close to the mesh site).

The management of sequelae of treatment and complications may involve reoperation (i.e. using the same laparoscopic technique used for the primary repair), conversion to another type of surgery (e.g. from laparoscopic to conventional open-mesh surgery, or from one type of laparoscopic technique to the other) or more conservative management strategies. This means that for several of the complications described above, there are a range of potential alternative management strategies, each of which has a specific set of potential resource (cost) implications.

Clinical event pathway description for laparoscopic techniques (TAPP vs TEP) for inguinal hernia repair

Clinical event	Inguinal hernia
Experimental interventions (comparison)	• Laparoscopic TAPP • Laparoscopic TEP
Resources used to manage clinical event (interventions)	• Duration of operation (minutes) • Anaesthetic drugs (dosage by type) • Post-operative inpatient hospital stay (days, hours) • Post-operative analgesics (dosage by type) • Post-operative follow-up outpatient visits (number)
Clinical outcomes of intervention (sequelae and complications)	• Hernia recurrence • Serious adverse events (including vascular injuries or visceral injuries) • Haematoma • Seroma • Wound/Superficial Infection • Mesh/Deep Infection • Port-site hernia • Time to return to usual activities (days) or time to return to work (days)

Resources used to manage clinical outcomes of intervention (sequelae and complications)	• Hernia Recurrence
	  o Conversion (see resources used to manage events)
	
	• Time to return to usual activities (days) or time to return to work (days)
	
	• Other health care resources used to manage sequelae and complications (various)
	
	[Clue: *Consider including the general outcome measure* (above) *instead of the potentially large number of complication-related resource use outcomes* (below)]
	
	• Vascular injuries
	  o Surgical ligation - increased operative time
	  o Transfer to monitored unit (if severe postoperative bleeding with hypotension and/or tachycardia)
	  o Intravenous fluid hydration (if severe postoperative bleeding with hypotension and/or tachycardia)
	  o Three hourly complete blood count (if severe postoperative bleeding with hypotension and/or tachycardia)
	  o Surgical re-investigation (if severe postoperative bleeding with hypotension and/or tachycardia and no response to intravenous fluid hydration)
	
	• Visceral injuries
	  o Simple observation

	o Primary repair (laparoscopy or laparotomy). • Haematoma o Expectant treatment with observation o Aspiration and drainage o Surgical management • Seroma o Expectant treatment with observation o Oral lysozyme o Aspiration and drainage o Oblique approach using small-diameter catheters • Wound/Superficial Infection o Removal of skin sutures; opening of wound and draining of pus o Irrigation with saline/Povidone Iodine o Gentle debridement of the wound o Antibiotic treatment. • Mesh/Deep Infection o Percutaneous drainage o Surgical removal of prosthesis (mesh) • Port-site hernia o Revisional surgery to reduce the port-site hernia (re-operation or conversion)
Cost of resources used to manage clinical event	• Average cost of each item of resource use listed under 'Resources used to manage clinical event' (per patient) • Average total direct health care costs of primary inguinal hernia repair (per patient) [*Cost of operative room time + cost of anaesthetic drugs + cost of post-operative inpatient hospital stay + cost of post-operative analgesics + cost of post-operative follow-up outpatient visits*]
Cost of resources used to manage clinical outcomes of intervention (sequelae and complications)	• Average total direct costs of conversion (per patient) • Average total direct costs of 'other health care resources used to manage sequelae and complications' (per patient) • Average total (lost) productivity costs (per patient)
Aggregated cost of resources used to manage clinical event + resources used to manage clinical outcomes of intervention (sequelae and complications)	• Average total direct health care costs (per patient) [*Cost of primary inguinal hernia repair + cost of managing sequelae and complications*]

Exercise

A. Highlight text that could be used in the 'BACKGROUND' section of the protocol to describe:
   i. the economic burden of the condition from the perspective of the health care system;
   ii. the economic burden of the condition from the perspective of the patient; and
   iii. the economic burden of the condition from the perspective of employers.

B. Based on the textual description only (i.e. not using the 'clinical event pathway description), describe the main potential impacts of using TEP rather than TAPP on the health care resources (costs) required to manage the primary surgical repair and immediate post-operative care?

C. Based on the textual description only, describe the main potential impacts of the choice between TAPP and TEP on:
   i. subsequent use of health care resources (sequelae and complications); and
   ii. subsequent use of non-health care resources.

D. Based on the text and clinical event pathway description, describe an objective for the economics component of a Cochrane review on this topic.

E. Based on the clinical event pathway description and your objective for the economics component of the review, add a list of potential measures of resource use, cost and cost-effectiveness to the list of 'types of outcome measures' that will be considered for inclusion in the review.

F. Based on the clinical event pathway description, your objective for the economics component of the review and your list of potential measures of resource use, cost and cost-effectiveness, describe the types of health economics studies that you will consider for inclusion in the review.

OBJECTIVES

1. To compare the clinical effectiveness of laparoscopic TAPP versus laparoscopic TEP for inguinal hernia repair.
2. [D. *Describe objective for the economics component of the review*] To critically appraise and summarise current evidence comparing the resource use, costs and cost-effectiveness of laparoscopic TAPP versus laparoscopic TEP for inguinal hernia repair.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All published and unpublished randomised controlled trials comparing laparoscopic TAPP with laparoscopic TEP. [E. *Describe types of health economics studies that will be considered for this review*] Full economic evaluations (including cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses), cost analyses and comparative resource utilisation studies conducted alongside randomised controlled trials comparing laparoscopic TAPP with laparoscopic TEP.

Types of participants

Adult patients requiring surgery for repair of inguinal hernia. Children (particularly under the age of 12) will be excluded since laparoscopic hernia repair is currently not recommended for these patients.

Types of intervention

Laparoscopic methods of surgical repair of inguinal hernia:

a) Laparoscopic TAPP
b) Laparoscopic TEP

Types of outcome measures

[*# Add measures of resource use/ cost/ cost-effectiveness to the list of clinical outcome measures below*]
Primary outcomes:
Hernia recurrence
Serious adverse events (including visceral injuries and vascular injuries)

Secondary outcomes:
Conversion

Haematoma
Seroma
Wound/Superficial Infection
Mesh/Deep Infection
Port-site hernia

Duration of operation (minutes)
Anaesthetic drugs (dosage by type)
Post-operative inpatient hospital stay (days, hours)
Post-operative analgesics (dosage by type)
Post-operative follow-up outpatient visits (number)

Health care resources used in conversion
Other health care resources used to manage sequelae and complications

Average (mean) cost of each item of health care resource use listed above (per patient)
Average (mean) total direct health care costs of primary inguinal hernia repair (per patient)
Average (mean) total direct health care costs (per patient)

Time to return to usual activities (days)/ time to return to work (days)
Average total (lost) productivity costs (per patient)

Measures of incremental cost-effectiveness (e.g. incremental cost-effectiveness ratios, incremental cost per QALY, incremental cost-benefit ratios, net benefits)