Minimal access surgery: an update

Naarilla A Hirsch

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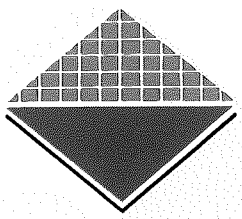

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Minimal access surgery: an update

A discussion paper

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Contents

Page

List of tables iv
Summary 1
Introduction 3
Laparoscopic procedures 8
- Laparoscopic cholecystectomy 11
- Laparoscopically assisted hysterectomy 17
- Laparoscopic appendicectomy 19
- Vagotomy 22
- Hernia repair 24
- Fundoplication 28
- Bowel resection 29
- Urology 30
- Diagnostic laparoscopy 30

Other procedures 34
- Arthroscopic surgery 34
- Hysteroscopic surgery 34
- Thoracoscopic surgery 35

Other issues 37
Conclusions 44
Appendix 1: Terminology and definitions 47
Appendix 2: Hospital morbidity data 50
Appendix 3: Cost estimates 51
References 54
Acknowledgements 62

List of tables

Page

Table 1: Summary of information about laparoscopic procedures 6

Table 2: Number of services attracting payments from the Medicare Benefits Schedule for selected surgical procedures by year 9

Table 3: Number of public hospital admissions for selected surgical procedures in 1991–92 for New South Wales, Victoria and South Australia 11

Table 4: Selected prospective studies comparing laparoscopic and open cholecystectomy 12

Table 5: Selected large observational studies of laparoscopic cholecystectomy 14

Table 6: Numbers of cholecystectomy procedures by year and type of procedure (at 1987–88 levels) 16

Table 7: Number of Medicare rebates for cholecystectomy by year and type of procedure 16

Table 8: Treatment cost ($) per patient for open and laparoscopic cholecystectomy 17

Table 9: Selected studies of laparoscopically assisted vaginal hysterectomy from 1993 18

Table 10: Selected prospective studies comparing laparoscopic and open appendicectomy 21

Table 11: Summary of cost estimates per patient episode of different procedures 22

Table 12: Selected prospective studies of laparoscopic hernia repair 26

Table 13: Average length of hospital stay (days) associated with hernia repair in New South Wales, Victoria and South Australia, 1991–92 28

Table 14: Selected prospective studies of laparoscopic bowel resection 29

Table 15: Number of services attracting payments from the Medicare Benefits Schedule for selected endoscopic and surgical procedures by year 32

Table 16: Number of Medicare Benefits payments for endometrial resection/ablation and hysterectomy by year 35

Table 17: Hysterectomies performed with a principal diagnosis of menorrhagia for 1988–89 and 1991–92 by State 35

Table 18: Issues in laparoscopic surgery 46

Table A3.1: Cost of selected equipment and instruments for laparoscopic surgery 52

Table A3.2: Cost of open surgery 52

Table A3.3: Cost of laparoscopic procedures 53

Summary

- This report summarises the status of laparoscopic surgery in Australia in early 1994, reviewing developments with the most significant procedures.
- **Laparoscopic cholecystectomy** has replaced most open cholecystectomies in Australia. The rate of diffusion of this technique has been very high; other laparoscopic methods are evolving more slowly. A higher rate of bile duct injury is of concern. Cost savings to the health care system have been eroded by increased cholecystectomy rates since the introduction of laparoscopic cholecystectomy. The laparoscopic method has produced cost savings and other benefits to society.
- **Laparoscopically assisted hysterectomy** may not offer cost advantages to the health care system. Serious complications are of concern. Limited numbers have been performed in Australia to date and endometrial ablation/resection is an alternative for some cases.
- **Laparoscopic appendicectomy** is safe and effective, but opinions differ as to its relative effectiveness in comparison with open appendicectomy. It may not offer cost advantages to the health care system. It has been in use at some centres in Australia for a number of years, with rates rising slowly.
- The safety and effectiveness of **laparoscopic vagotomy** have yet to be determined. It may replace some open vagotomy and medical treatment.
- Techniques for **laparoscopic repair of groin hernias** are still developing. The relative safety in comparison with open alternatives is of concern, and long-term recurrence rates are unknown. Cost advantages to the health care system may be small or non-existent.
- Like laparoscopic vagotomy, **laparoscopic fundoplication** has not been proven safe and effective, but has the potential to impact on high-cost medical treatment as well as open surgery.
- **Laparoscopic bowel resection** requires considerable skill and training, and has not been proven more effective or safer than open surgery.
- **Laparoscopic techniques** are diffusing more slowly **in urology** than in general surgery, and their role is yet to be determined.
- **Laparoscopy** has an emerging role **in the diagnostic area** complementary to conventional scanning techniques. Its comparative accuracy is not well established to date.
- **Thoracoscopic techniques** have been developed for a number of open procedures. For procedures such as lung biopsies, excision of cysts and sympathectomy, the thoracoscopic technique may become the preferred approach, but its role has not been determined for other procedures.
- Difficulty in performing procedures laparoscopically appears to have changed standard surgical practice in at least one instance.
- Instrumentation and equipment are evolving rapidly, confronting hospitals with issues of the timing and costs of upgrades. Relative overall costs of disposable and reusable instruments are still uncertain.
- The safety of laparoscopic techniques and training in their use remain important issues.

- Other issues that have arisen include:
  - use of laparoscopic procedures in day surgery;
  - public demand and funding mechanisms driving diffusion of new procedures before their safety and cost-effectiveness are established;
  - changes to hospital infrastructure;
  - the cost of major complications.
- Further work is needed to determine:
  - safety and effectiveness of some laparoscopic procedures;
  - relative advantages and disadvantages of other laparoscopic procedures over open surgical alternatives;
  - long-term complication and recurrence rates.

Introduction

Minimal access surgery (MAS) has significant potential advantages over open surgery. In an open operation, not only is there a large wound, but retraction, handling and direct trauma by instruments cause tissue damage, exposure, cooling and drying of the internal structures. The consequences are post-operative pain, hospital stays which are often over a week, and prolonged convalescence, which is often up to six weeks. Complications include infection, fever, nerve damage, pneumonia, blood clots and excessive bleeding.[1,2]

A major advantage of MAS is that by minimising the size of the wound it also reduces post-operative trauma, thereby shortening hospital stays and convalescence. For example, many patients can be discharged from hospital one to two days after a laparoscopic cholecystectomy and typically return to work or normal activity within a week.[3,4] Comparable periods for the open surgery alternative were discharge seven days after operation and return to normal activities in six weeks.[5] Many of the complications of open surgery are minimised, although those specific to laparoscopy, such as damage to blood vessels and organs, are potentially serious. As well as benefits to patients there is the prospect of reduced costs to both the health care system and employers.

MAS has already had a significant impact in some areas. The use of laparoscopy is well established in gynecology. Endoscopy has been a useful diagnostic technique for some time, as well as being used for simple therapeutic procedures such as removal of foreign bodies. Major surgical applications in laparoscopy, arthroscopy and hysteroscopy have been established in the past few years and more are expected in the near future.

The application of laparoscopic or 'keyhole' surgery to general surgery is one of the most significant of these developments. Over the past four years laparoscopic cholecystectomy has replaced most open cholecystectomies and become the standard of care for gallstone disease. Laparoscopic appendicectomy and repair of femoral and inguinal hernias are being performed in a number of hospitals in Australia and, as with laparoscopic cholecystectomy, items covering these methods have been added to the Medicare Benefits Schedule. Laparoscopic versions of many other open abdominal and pelvic procedures have been developed and are continuing to be investigated to determine their safety, efficacy and future role.

In 1992 the Australian Institute of Health and Welfare published a discussion paper that considered current and potential developments in MAS and the issues they raise.[6] Since then, the area has continued to develop and further information has become available.

This report considers some of the changes that have occurred since the first paper. It identifies many of the more significant new procedures and considers their effectiveness and cost implications. In the light of the better information available, it considers the potential impact of the 'laparoscopic revolution' and discusses issues raised by it. A comprehensive review of the literature and all developments in MAS has not been attempted. Rather, the report focuses on those areas in which MAS has the greatest potential to make a significant impact, in the short term, on costs to health services and to health status. Even with this restriction, the available literature is large and expanding rapidly. The review is based on literature available to the Institute up to March 1994. The focus of the literature review was on those reports which included objective measures, outcomes and costs.

The paper has been prepared to provide a basis for comment and discussion by health authorities, hospital planners, professional bodies and other organisations with an interest in this area and as source material for the Australian Health Technology Advisory Committee.

Terminology and definitions applying to the report, and a glossary, are in Appendix 1.

Current status of laparoscopic methods

The general status of the most significant areas for MAS procedures in early 1994 is summarised in Table 1 (pages 6–7), which is based on the literature review, discussions with practitioners and databases available to the Institute.

Laparoscopic cholecystectomy is now widely established and is used for the large majority of procedures for removal of the gall bladder. The diffusion of this MAS technique has been particularly rapid and widespread in comparison with many other health care technologies.

The other laparoscopic surgical methods are developing and coming into use more slowly, in part because of perceived limited advantage over conventional methods and because of technical difficulty.

Outcome and cost data for MAS methods remain limited and there are still few controlled studies.

Developments in procedures

The introduction of laparoscopic cholecystectomy was quickly followed by use of laparoscopic approaches in many abdominal and pelvic operations, some of which were listed in the previous report.[6] Recent changes have primarily concerned developments in surgical technique and of alternative techniques for specific procedures already performed laparoscopically. For example, several different techniques of hernia repair have been developed. However, the most appropriate technique in terms of outcome and long-term recurrence rates is yet to be established.

With laparoscopically assisted hysterectomy (LAH) the need for preliminary uteric dissection is being debated.[7] Several different colonic techniques have been developed, but concerns about the procedures include the possibility of tumour spillage, the best technique for retrieval of large segments of colon, and the use of laparoscopic colonic resection as a curative procedure for malignancy.[8,9] Developments in technique are ongoing and will establish the best laparoscopic approach for each type of procedure and, to some extent, determine its role in relation to conventional surgery and other MIT techniques.

Developments in instrumentation and equipment

Developments in instrumentation and equipment have played a major role in the spread of the laparoscopic approach into general and urological surgery. Laparoscopic cholecystectomy was made possible by developments such as specialised clip appliers and high-resolution sterile video cameras with high-powered light sources. Laparoscopic staplers have aided the development of other procedures such as hernia repair and LAH.

Some current developments in equipment are incremental changes to make procedures quicker and easier. For example, laparoscopes with articulating tips or with their own irrigation have been developed, and also flexible small endoscopes that can be used in conjunction with rigid scopes.[10] A flexible laparoscope is claimed to be able to perform a more thorough exploration of the abdomen and possibly reduce the need for an assortment of oblique viewing rigid laparoscopes.[11] An endoscopic ultrasonic dissection device has been developed and could offer an alternative to monopolar diathermy, which has a potential for causing burns near or remote from the site of application. The diffusion of such incremental changes depends on factors such as their cost and perceived usefulness in comparison with equipment already in use.

Other developments may be more significant. Lack of depth of vision has been a major disadvantage of laparoscopic surgery, affecting performance of complex tasks such as

suturing and posing difficulties for some surgeons in the transition from open to laparoscopic techniques.[12] To solve this problem, video systems with three-dimensional optics and enhanced video resolution have been developed.

Gas embolism caused by the pneumoperitoneum is a serious complication of laparoscopic surgery. Devices to lift the abdominal wall to create space for the procedure without insufflating large volumes of gas have been developed, with promising early results.[13,14] However, the large retractors used produce an awkwardly shaped cavity (Hugh, personal communication). These devices need further refinement, but allow use of conventional instruments, with implications for instrument costs.[15]

A large range of laparoscopic instruments has been developed for specific applications, examples being bowel clamps, liver elevators, cholangiogram forceps, pediatric forceps and scissors, thoracoscopic trocars and a variety of graspers and dissectors. Much of the initial development in instrumentation was with disposable or single-use instruments, with fewer reusable laparoscopic instruments being available. In the past two years, more sophisticated reusable instruments have become available, although not reusable versions of the more complex staplers. Reusable instruments can now be rotated easily during a procedure and come completely apart for cleaning. Semi-disposable instruments allow parts to be replaced when worn, such as the jaws of scissors. There is a trend towards detachable instruments, allowing different combinations of shafts and handles. Limited reusable instruments have also been developed.

Other issues relating to instruments and equipment are considered on page 41. In general, while incremental advances can be expected to continue, there is a lack of evidence as to the comparative advantage of some of the newer developments, and the cost consequences to hospitals and other purchasers are unclear.

Table 1: *Summary of information about laparoscopic procedures*

Procedure	National caseload[a]	Potential level of replacement[b]	Effectiveness	Safety	Cost issues	Status	Comments
Laparoscopic cholecystectomy	Historically 25,000–27,000; now over 30,000	At least 80%	Proven effective; more effective than open cholecystectomy	Low morbidity and mortality; higher rate of bile duct injury than open cholecystectomy	Cheaper per patient but savings overall for health care system may be limited	Established; replaced 80% of open cholecystectomies on the MBS	Initial high conversion rate now declining; increase in rate of cholecystectomy
Laparoscopically assisted hysterectomy	30,000 (61% being abdominal hysterectomies)	Uncertain; some or many abdominal hysterectomies	Not proven; early results promising	Concerns about complication rate	Cost per patient uncertain, but may differ little from abdominal hysterectomy	Developing	Impact on vaginal hysterectomy limited; endometrial ablation competing for same diagnoses
Laparoscopic appendicectomy	25,000–30,000	Uncertain	Proven effective; different opinions on its relative effectiveness compared with open appendicectomy	Proven safe	Cost per patient may differ little from open appendicectomy	Established; diffusion unknown; on the MBS	Unclear if offers significant advantages over open appendicectomy
Laparoscopic (groin) hernia repair	Over 30,000	Uncertain	Not proven; long-term recurrence rates unknown	Not unsafe, but concerns about rates of neurological and other complications	Cost per patient may differ little from open hernia repair	Evolving; diffusion unknown; on the MBS	Role as part of the range of hernia repair techniques is not clear
Laparoscopic vagotomy	Under 2,000	Could replace much open vagotomy	Not proven; not clear which of available approaches is most effective	Not proven	Cheaper per patient than open vagotomy; may impact on cost of medical therapy	Developing	Could also impact on medical therapy; roles of laparoscopic vagotomy, bacteria eradication and existing therapies not clear
Laparoscopic fundoplication	Under 2,000	Could replace much open fundoplication	Not proven	Not proven; complications significant in some patients	Cheaper per patient than open fundoplication; may impact on cost of medical therapy	Developing	Could also impact on medical therapy; roles of laparoscopic fundoplication and existing therapies not clear; long learning curve

Table 1 (continued): *Summary of information about laparoscopic procedures*

Procedure	National caseload[a]	Potential level of replacement[b]	Effectiveness	Safety	Cost issues	Status	Comments
Laparoscopic bowel resection	5,000–10,000	Uncertain	Not proven; no advantages over open approach proven	Not proven; concerns about some complications	Unclear	Developing	Considerable skill and training needed
Laparoscopic procedures in urology	5,000 or less for individual procedures	A number of urological procedures have been performed laparoscopically. Effectiveness, safety and advantages over open alternatives are yet to be proven for most. Diffusion slower than in general surgery.					
Diagnostic laparoscopy	Uncertain	Has an emerging role complementary to conventional scanning techniques. More invasive than scanning techniques, with potential for serious complications.					
Thoracoscopic procedures	Small (under 3,500 overall)	A number of thoracoscopic procedures have been developed. Some thoracoscopic techniques may become the preferred approach, but the role of others is unclear. Further comparative studies are needed to establish the effectiveness, safety and relative role of individual techniques.					

MBS Medical Benefits Schedule

(a) Of both the laparoscopic procedure and its open alternative

(b) Of open alternative by laparoscopic procedure

Laparoscopic procedures

Early predictions were that laparoscopic techniques would replace most abdominal surgery. In considering which procedures might be replaced by laparoscopic alternatives, a number of factors are important:

- Is the main cause of post-operative pain and slow recovery due to the incision? If so, a laparoscopic approach should significantly reduce post-operative pain, and shorten hospital stays and recovery periods.
- Is the laparoscopic technique as safe and efficacious as the procedure it is replacing?
- Is the laparoscopic technique cost-effective in comparison with alternatives?

Some laparoscopic techniques might remain so technically difficult or offer little advantage in comparison with open alternatives that they have limited application. With others, the advantages may be so clear-cut that within a short period the laparoscopic approach is regarded as the standard procedure, as has already occurred with laparoscopic cholecystectomy.

Laparoscopic versions of many abdominal procedures have been reported. Those that are more significant in terms of their potential impact upon the health care system have been selected for detailed evaluation. Inferences about the remainder can be made by analogy with those procedures studied. The procedures selected are:

- cholecystectomy;
- hysterectomy;
- appendicectomy;
- vagotomy;
- hernia repair;
- fundoplication;
- bowel resection;
- urological applications;
- diagnostic laparoscopy.

Laparoscopic approaches to cholecystectomy, appendicectomy, hernia repair and hysterectomy are of considerable interest in view of the large volumes of each performed annually (Tables 1 to 3). While volumes of individual urological procedures are not large, overall they represent a significant volume and are consequently of interest.

Ulcers are a significant health problem, with anti-ulcerants representing 1.1% of all drugs prescribed by GPs.[16] The annual incidence of ulcers in Australia has been estimated at 3.8 per 1,000 population for duodenal ulcers and 0.7 for gastric ulcers.[17] Treatment is most often medical, with low rates of surgical intervention (Tables 2 and 3). However, laparoscopic vagotomy has been suggested as an alternative to medical treatment and so is of considerable interest. Laparoscopic fundoplication for anti-reflux disorders has been included for similar reasons.

Bowel resection is another procedure where the annual caseload is not large. However, the laparoscopic approach is of a higher degree of technical difficulty than procedures such as laparoscopic cholecystectomy or appendicectomy and has been included as an example of such difficult operations.

Table 2: *Number of services attracting payments from the Medical Benefits Schedule for selected surgical procedures by year*

Type of procedure	Current item no	1988–89	1989–90	1990–91	1991–92	1992–93
Hernia						
Repair of ventral, incisional or recurrent hernia	30403, 30405	4,084	4,309	4,394	4,961	4,195
Repair of strangulated, incarcerated or obstructed hernia	30615	1,087	1,072	1,171	1,228	1,475
Repair of other femoral or inguinal hernia (open)	30613, 30614	19,182	19,370	19,995	20,253	21,049
Repair of other hernias	30600, 30601, 30616 to 30621	3,282	3,373	3,688	3,929	4,408
Repair of all hernias		*27,635*	*28,124*	*29,248*	*30,371*	*31,847*
Gastrointestinal tract						
Appendicectomy through open incision	30571, 30574	13,739	12,572	12,169	11,277	9,974
Laparoscopic appendicectomy	30572	–	–	–	–	884(a)
Cholecystectomy (open)	30443	12,561	12,551	11,646	5,004	2,430
Laparoscopic cholecystectomy	30445 to 30449	–	–	1,984	13,863	14,759
Choledochotomy	30454 to 30457	1,684	1,653	1,404	940	705
Liver biopsy	30409 to 30412	1,232	1,347	1,387	1,542	1,054
Vagotomy	30496 to 30503	496	400	336	311	202
Anti-reflux operation	30527 to 30530	703	675	733	652	876
Hemicolectomy or total colectomy	32006 to 32021	2,425	2,559	2,015	1,514	1,091
Urology						
Orchidectomy	30638, 30641	1,867	1,828	2,550	2,553	2,646
Other removal or tapping of hydrocele	30628, 30631	1,737	2,279	2,939	3,121	3,360
Other surgical correction of varicocele	30634, 30635	2,480	1,756	1,259	1,242	1,082
Orchidopexy or transplantation of undescended testis	30647	2,659	2,585	2,368	2,299	2,218
Laparotomy						
Exploratory laparotomy	30373	1,096	1,104	1,095	1,046	928
Laparotomy involving division of adhesions	30376 to 30379	2,696	2,785	2,890	3,594	3,907
Laparotomy involving operations on abdominal viscera	30375	2,935	2,914	2,825	2,711	2,409
Other laparotomy	30384 to 30388, 30394, 30396, 30400	2,536	2,678	3,480	3,243	3,167
All laparotomy		*9,263*	*9,481*	*10,290*	*10,594*	*10,411*

Table 2 (continued): *Number of services attracting payments from the Medical Benefits Schedule for selected surgical procedures by year*

Type of procedure	Current item no	1988–89	1989–90	1990–91	1991–92	1992–93
Gynecology						
Hysterectomy	35653 to 35673	20,590	20,408	19,719	19,845	20,409
Other laparotomy	35712 to 35717	6,671	6,308	6,184	6,004	4,923
Removal of ectopic gestation	35676, 35677	1,409	1,374	1,362	1,199	790
Laparoscopic removal of ectopic gestation	35678	–	–	–	–	357(a)
Repair of Fallopian tube	35694 to 35700	2,598	2,389	2,527	2,399	1,756
Thoracic						
Exploratory thoracotomy	38414	471	468	418	470	424
Other thoracotomy	38421, 38424, 38446	416	406	414	439	440
Pneumonectomy, lobectomy or segmentectomy	38438, 38441	572	609	609	634	603
Wedge resection of lung	38440	–	–	–	–	103(a)

(a) New item since November 1992

Source: Health Insurance Commission; Commonwealth Department of Human Services and Health

Table 3: *Number of public hospital admissions for selected surgical procedures in 1991–92 for New South Wales, Victoria and South Australia*

Type of procedure	Number of admissions
Hernia	
Repair of inguinal hernia	14,705
Repair of femoral hernia	857
Repair of all hernias	21,134
Gastrointestinal tract	
Appendicectomy	16,432
Cholecystectomy	14,531
Percutaneous liver biopsy	3,498
Vagotomy	423
Hemicolectomy, total colectomy or other large intestinal excision or anastomosis	5,761
Urology	
Orchidectomy	1,834
Laparotomy	
Laparotomy for division of adhesions	5,753
Laparotomy for exploration, control of bleeding or drainage of abscess	3,410
Gynecology	
Hysterectomy	12,421

Source: State health authorities hospital morbidity data, see Appendix 2

Diagnostic laparoscopy, while not strictly part of minimal access surgery, has been included in this section since it has also been affected by recent changes in technology. Its use has extended from gynecology to general surgery, where it has been used for a variety of applications, including staging or excluding cancer, investigating trauma cases and abdominal pain, and performing biopsies. It potentially will complement some and avoid other forms of investigation, such as computerised tomography (CT) scanning, laparotomy and diagnostic peritoneal lavage.

Laparoscopic cholecystectomy

Safety and effectiveness

Laparoscopic cholecystectomy has replaced open cholecystectomy as the surgical treatment of choice for gallstone disease. This occurred over a period when there was very limited published information comparing the relative effectiveness of the two procedures. Since then some prospective comparative studies of the two procedures have emerged (Table 4). Results of larger observational studies are also available (Table 5). These indicate that the laparoscopic approach is more effective than open cholecystectomy. As was originally claimed, hospital stays and recovery periods are shorter following laparoscopic cholecystectomy and post-operative analgesia requirements are less. However, Hardy et al. have commented that attitude and habit may be important factors in determining length of hospital stays.[18]

Table 4: *Selected prospective studies comparing laparoscopic and open cholecystectomy*

Characteristics	Barkum et al. (1992)	Attwood et al. (1992)	Kelley et al. (1993)	St Vincent's Hospital Melb (1992)	Trondsen et al. (1993)	Hardy et al. (1994)
Method of sample selection	Random	Consecutive	Clinical [a]	Clinical [a]	Random	[b]
Sample size:						
laparoscopic	37	63	196	100	35	108
open	25	52	82	100	35	108
Mean age of sample (years):						
laparoscopic	51.4	52	45.3	n.a.	43	43.5
open	52.3	51	45.5	n.a.	55	50.5
Average hospital stay (days):						
laparoscopic	3 [c]	n.a.	1.3	5.5	2 [c,d]	2.0 [d]
open	4 [c]	n.a.	3.7	8.7	4 [c,d]	6.5 [d]
Average time to return to work (days):						
laparoscopic	11.9	n.a.	8.2	12	11 [c]	16.3
open	20.2	n.a.	42.8	43	34 [c]	35.2
Mean operation time (minutes):						
laparoscopic	85.9	n.a.	90.6	82.2	100 [c]	164
open	73.1	n.a.	96.6	72.8	50 [c]	131
Laparoscopic procedures converted to open (%)	0	5.0	5.6	0 [e]	5.7	4.5
Complication rates (%):						
Wound infection:						
laparoscopic	0	7.9	0	n.a.	0	16.6 [f]
open	4.0	3.8	0	n.a.	0	10.3 [f]
Bile duct injury:						
laparoscopic	0	0	0	0	0	0
open	0	1.9	0	0	0	0
Other:						
laparoscopic	2.7	1.6	3.1	16 [g]	17.1	n.a.
open	4.0	0	2.4	13 [g]	20.0	n.a.

Table 4 (continued): *Selected prospective studies comparing laparoscopic and open cholecystectomy*

Characteristics	Barkum et al. (1992)	Attwood et al. (1992)	Kelley et al. (1993)	St Vincent's Hospital Melb (1992)	Trondsen et al. (1993)	Hardy et al. (1994)
Mortality:						
laparoscopic	0	0	0	0	0	0
open	0	0	0	0	0	0

n.a. Not available

(a) Patient assignment to different arms of trial made on basis of clinical decision and assessment of indications

(b) Laparoscopic cholecystectomy group compared with retrospective matched open cholecystectomy group who had been studied prospectively during surgical audit.

(c) Median, not mean

(d) Post-operative

(e) Experience at the hospital outside this trial indicates a 14.6% conversion rate.

(f) Late wound infection

(g) All complications

Source: References 5, 18–22

Table 5: *Selected large observational studies of laparoscopic cholecystectomy*

Characteristics	Southern Surgeons Club (1991)	Cuschieri et al. (1991)	Soper & Dunnegan (1993)	Go, Schol & Gouma (1993)	Orlando et al. (1993)	Perissat et al. (1992)
Method of sample selection	Prospective, multi-centre	Retrospective, multi-centre, survey	Prospective, single surgeon	Retrospective, multi-centre, survey	Retrospective, multi-centre	Single centre
Sample size	1,518	1,236	415	6,076	4,640	777
Mean age of sample (years)	47	47 (a)	48	n.a.	n.a.	n.a.
Average hospital stay (days)	1.2	3 (a)	1.1	4.5 (b)	3	2.8 (c)
Average time to return to work (days)	n.a.	11 (a)	8.5	n.a.	n.a.	n.a.
Mean operation time (minutes)	90	50 (a)	95	70 (b)	n.a.	n.a.
Laparoscopic procedures converted to open (%)	4.7	3.6	1.9	6.8	6.9	5.5
Complication rates (%):						
Wound infections	1.0	0.2 (d)	0.9	1.65	n.a.	n.a.
Bile duct injury	0.5	0.2 (d)	0.2	0.86	0.3	0.4
Other	3.6	0.3 (d)	3.3	1.79	8.3	3.3
Mortality	0.07	0	0	0.12	0.13	0.1

n.a. Not available

(a) Median, not mean

(b) For most recent 10 patients in each centre.

(c) Post-operative stay for those patients with no complications or conversion to laparotomy in group of 617 patients

(d) Major complications only. Total complication rate was 1.6 per cent.

Source: References 23–28

Laparoscopic cholecystectomy is considered to be a safe procedure with low morbidity and mortality rates. However, bile duct injury occurs more frequently than during open cholecystectomy, so that there is an increased risk of uncommon major complications. Deziel et al. report the rate of major bile duct injury to be 0.6% in the USA[29] and a similar rate has been suggested for Australia.[30] Bernard and Hartman conclude that the rate of bile duct injury is seven to fifteen times greater than that for open cholecystectomy.[31] Bowel and vascular injuries are other major complications of laparoscopic cholecystectomy and are the technical complications most likely to be associated with death.[29,31]

Adequate training is crucial in avoiding such injuries. Complication rates are higher early in surgeons' experiences. Good surgical technique and accurate identification of the anatomy are also important factors. The Royal Australasian College of Surgeons (RACS) has issued training recommendations for laparoscopic cholecystectomy, and technical recommendations to minimise morbidity following laparoscopic cholecystectomy have emerged recently.[30,32]

Diffusion

Laparoscopic cholecystectomy was the first of the new laparoscopic techniques in general surgery to diffuse, and did so very rapidly. Within two years of its introduction to Australia, an estimated 73.5% of the cholecystectomy caseload was attempted using the laparoscopic approach, with 63.0% being successfully completed laparoscopically.[33] By the following year, an estimated 78.4% was being attempted laparoscopically, with 72.4% being completed successfully using this approach.

One notable feature about the diffusion of laparoscopic cholecystectomy is that, since its introduction, the rate of cholecystectomy (at a constant population level) has increased (Table 6). Prior to its introduction, this rate was relatively constant. Numbers of cholecystectomies attracting Medicare Benefits payments rose dramatically between 1990–91 and 1991–92, and there was also a major increase in public hospital procedures as indicated by hospital morbidity data. Numbers of cholecystectomies attracting Medicare Benefits payments fell again in 1992–93, though they are still substantially higher than historical levels (Table 7). Whether this represents a fall in the total number of cholecystectomies performed or a shift from the private to the public sector will not be clear until hospital morbidity data are available for 1992–93.

Similar increases in cholecystectomy rates have been noted in other countries. In Canada, the rate of cholecystectomy had increased by 17% in 1991–92, compared with pre-laparoscopic levels.[33] In New York there has been a 21% increase between 1988 and 1991 in total number of cholecystectomies performed.[31] A 29% increase since the introduction of the laparoscopic approach has been noted in Connecticut.[27]

In Maryland the rate of cholecystectomy increased by 28% between 1989 and 1992, with a plateau near the end of this period.[34] During this period the overall mortality rate for all cholecystectomies decreased, but the number of operative deaths from cholecystectomy remained constant due to the increased cholecystectomy rate. Legorreta et al. report a 57% increase in the rate of cholecystectomy in patients enrolled in a health maintenance organisation in Pennsylvania between 1988 and 1992.[35] They consider a change in the perceived risk-benefit ratio for the procedure, leading to a change in its indications, to be the most likely explanation for this increase.

Several factors have been suggested as possible reasons for these increases in rates.[33] Firstly, laparoscopic cholecystectomy might be being offered to frailer patients who would not otherwise be candidates for surgery. However, careful judgement in such patient selection would be needed since a proportion of laparoscopic procedures are converted to open operations.

Availability of laparoscopic cholecystectomy may increase the probability of surgical intervention in symptomatic patients who are potential candidates for open surgery, and decrease the likelihood of conservative management. The new techniques might be seen as providing better opportunities to definitively resolve a clinical problem.

Table 6: *Numbers of cholecystectomy procedures by year and type of procedure (at 1987–88 levels)*

Year	Open procedures	Laparoscopic procedures	Converted laparoscopic procedures	Total cholecystectomies
1987–88	27,248	–	–	27,248
1988–89	27,198	–	–	27,198
1989–90	25,422	–	–	25,422
1990–91	21,363	2,836	803	25,002
1991–92	8,977	21,343	3,557	33,877
1992–93[a]	6,390	22,030	1,826	30,428

(a) Note that while data for earlier years is based on both Medicare and hospital morbidity data, only Medicare data was available to derive data for this year.

Source: References 36,37

Table 7: *Number of Medicare rebates for cholecystectomy by year and type of procedure*

Year	Open procedures	Laparoscopic procedures	Total cholecystectomies
1987–88	12,373	–	12,373
1988–89	12,561	–	12,561
1989–90	12,551	–	12,551
1990–91	11,646	1,984	13,630
1991–92	5,004	13,863	18,867
1992–93	2,405	14,759	17,164

Source: Commonwealth Department of Human Services and Health, Health Insurance Commission

Another possibility is that laparoscopic cholecystectomy is being offered in asymptomatic cases, for instance when gallstones are detected during an unrelated imaging examination. Finally, the technique might at times be offered following inappropriate diagnosis, with part of the rationale being that the procedure is much less invasive.[38]

Another feature of the introduction of this method was that the rate of conversion of laparoscopic procedures to open surgery in Australia was 14.3% in 1991–92, substantially higher than the Canadian rate of 4.2% and other published values.[33] The rate has fallen as experience has been gained, to an average of 8.4% in 1992–93, with variations of 4.9% to 12.8% in different States.[36]

Costs

Estimates of hospital and total costs for laparoscopic and open cholecystectomy (Table 8) clearly show the cost advantages of the laparoscopic approach over an open approach on a per patient basis. Analysis of the procedures in terms of healthy year equivalents confirms the superiority of the laparoscopic approach.[39] An analysis of clinical costs in an Australian hospital found that the laparoscopic approach was $850 cheaper, with savings from the shorter hospital stay in part offset by a higher operating room cost.[18] Bass et al. reach a similar conclusion in the United States, provided that laparoscopic cholecystectomy does not routinely require pre-operative cholangiography and is not associated with increased professional fees or increased risks of retained stores or bile duct injury.[40] The Canadian Coordinating Office of Health Technology Assessment estimated that the weighted average cost of laparoscopic cholecystectomy was $2,687 less than that of open cholecystectomy .[37] In

the United Kingdom, Fullarton et al. have concluded that, after the initial learning period, hospital costs for laparoscopic cholecystectomy are lower than those for open cholecystectomy.[41] A Quebec study differs and concludes that, in terms of the hospital budget, there is very little difference in cost between laparoscopic and open cholecystectomy.[42]

When the total cost to the health care system is considered, the advantages of laparoscopic cholecystectomy are not as clear-cut. The increases in caseload already noted either partially or completely offset the cost benefits obtained by decreasing the unit cost of cholecystectomy. Despite a fall of 25.1% in the unit cost of cholecystectomy due to use of the laparoscopic approach, Legorreta et al. found an 11.4% increase in the total cost of the procedure per head of population serviced, due to the increased caseload.[35] Similarly, despite significant falls in the estimated unit costs of cholecystectomy, neither Canada nor Australia achieved the expected cost savings from the laparoscopic approach during the first two years following its introduction.[37] A preliminary estimate is that in 1991–92 Canada achieved approximately 37% of the potential savings in health program costs, and Australia made only 24% of its potential savings. In Australia, costs of cholecystectomies to the health care system have fallen from $120m in 1987–88 to only $114m per year in 1991–92.[37]

The costs of cholecystectomy to patients, their families and employers include the cost of time lost from paid work, home duties and leisure activities, travel costs and the cost of carers. Estimates of these costs for laparoscopic and open cholecystectomy suggest significant advantages for the laparoscopic approach (Table 8). Despite the increased cholecystectomy caseload since the laparoscopic approach was introduced, estimates of savings to society show a considerable advantage to the laparoscopic approach. There has been a 25% decrease in days lost by patients annually, and savings to society (not health programs) of $26m to $37m a year.[37]

Table 8: *Treatment cost ($) per patient for open and laparoscopic cholecystectomy*

Type of cost	Open cholecystectomy	Laparoscopic cholecystectomy
Hospital costs	3,053 to 3,366	2,393 to 2,581
Indirect and patient costs	3,235 to 4,340	1,416 to 1,831
Adjustment for conversion to open surgery	–	272 to 302
Total costs	**6,288 to 7,706**	**4,081 to 4,714**

Source: Reference 43

Laparoscopically assisted hysterectomy

Safety and effectiveness

Published information about the effectiveness of laparoscopically assisted vaginal hysterectomy (LAH) is limited. An earlier assessment of LAH and alternatives concluded that, while early results appear promising in terms of the success and morbidity of LAH, there is clearly a need for further research to be done into its safety and efficacy in comparison with abdominal and vaginal hysterectomy.[44] There is little reason to modify this conclusion, since only limited additional data have appeared since this report (summarised in Table 9).

A major concern with LAH is the complication rate. While early results indicate a lower complication rate than for abdominal hysterectomy, serious injuries can occur, especially during the surgeon's learning curve. A 12% rate of conversion to laparotomy because of complications such as vascular, small bowel and ureteral injuries has

Table 9: *Selected studies of laparoscopically assisted vaginal hysterectomy from 1993*

Characteristics	Jones (1993)	Boike et al. (1993)			Phipps & Nayak (1993)		Daniell et al. (1993)	Lee & Soong (1993)
	LAH	AH	VH	LAH	AH	LAH	LAH	LAH
Method of sample selection	Prospective	Retrospective, comparative chart review			Prospective, random		Multi-hospital	n.a.
Sample size	100	50	50	50	24	29	68	82
Mean age of sample (years)	48	48	51	48	44	41	38	4.3
Average hospital stay (days)	3.3 (a)	4.5	3.8	2.5	2.0(a,b)	6.0(a,b)	2.6	2.6
Average time to return to work (days)	22	n.a.	n.a.	n.a.	2(b)	6(b)	19	n.a.
Mean operation time (minutes)	89	163	176	240	65	30	136(c)	152
Laparoscopic procedures converted to open (%)	1.0	–	–	n.a.	–	n.a.	8.8	n.a.
Complication rates (%):		26		12				
Wound infection	0	n.a.	0	n.a.	0	0	2.9	0
Ureteral and bladder injuries	4	n.a.	0	n.a.	0	0	0	2.4
Other	19 (d)	n.a.	6	n.a.	0	0	2.9	4.9
Mortality	0	0	0	0	0	0	0	0

LAH Laparoscopically assisted hysterectomy

AH Abdominal hysterectomy

VH Vaginal hysterectomy

n.a. Not available

(a) Post-operatively

(b) Median

(c) 117 mins when stapling device was used, 223 mins when diathermy was used

(d) Calculated from total number of complications rather than number of patients with complications

Source: References 45–49

occurred. Other complications include vaginal vault hematomas, bladder perforation, transient nerve injuries and fluid overload.[50,51] While adequate training, experience and refinement of both equipment and surgical technique should prevent some of these injuries, the major complication rate of LAH in clinical practice is not known.

Costs

The financial cost per patient episode of LAH was estimated as $2,960 in Australia at the end of 1992, compared with $3,740 and $3,550 for abdominal and vaginal hysterectomy respectively.[44] The LAH cost included $1,200 for disposable instruments. If some reusables are used instead, the procedure cost would be lower.

This LAH cost estimate also assumes an average hospital stay of 1.7 days and 6.5% rate of conversion to laparotomy, based on values available from the literature at the time. If currently available laparoscopic cholecystectomy values of 2.5 days in hospital and an 8.4% conversion rate to laparotomy are used instead,[36] the cost per patient episode of LAH becomes $3,340, little less than the cost of alternative forms of hysterectomy. A Brisbane private hospital found its average financial cost for LAH in 1992 to be $4,326, higher than that of abdominal hysterectomy ($4,024).[52] As well, US data suggest that, in that country, patient charges for LAH are in fact 17% higher than those for abdominal hysterectomy.[46] Another US study found that, unless diathermy is used instead of a stapling device, hospital costs of LAH are considerably higher than those of abdominal hysterectomy.[48] It can be concluded that costs of LAH to the health care system are uncertain. Whether the procedure will cost much less than more traditional approaches to hysterectomy will depend on lengths of hospital stays, conversion rates to open operations and the mix of disposable and reusable instruments in routine clinical use.

In 1991–92, non-radical hysterectomies imposed a financial cost of approximately $100m on the health care system.[53] The potential effect of LAH upon this level of expenditure is difficult to gauge since it is not clear how many abdominal hysterectomies are likely to be replaced by LAH. If 50% were replaced and the financial cost of LAH were $2,960, as discussed previously, then the health care system would be saved an estimated $15m per year. If, however, the procedure cost turns out to be the higher level of $3,340, then annual savings to the health care system are relatively modest (only $4m).

In Australia in 1991–92 an estimated 3,175 person years were lost from work or other activities due to non-radical hysterectomies.[53] If 50% of abdominal hysterectomies were to be replaced by LAH, then 750 person years less would be lost from work or other activities, independent of the direct costs of the procedures. Further work is necessary to ascertain the safety, efficacy and cost-effectiveness of LAH in comparison with abdominal and vaginal hysterectomy, and to determine the role of this procedure, relative not just to other forms of hysterectomy but also to endometrial resection/ablation.

Laparoscopic appendicectomy

Safety and effectiveness

Laparoscopic appendicectomy has for some years been part of the armamentarium of the gynecologist in diagnosing and treating chronic or recurring lower abdominal pain in young women. Its use has now spread to treatment of acute appendicitis in the emergency situation.

A number of studies report satisfactory results with treating series of patients with laparoscopic appendicectomy. Some of these include incidental appendicectomies on young women and consequently may present more positive results than would be likely in the acute setting. While the number of patients in some series is quite small,

several larger studies have concluded that laparoscopic appendicectomy is safe and effective.[54-56] Advantages over the open approach cited include less scarring, decreased formation of adhesions and disruption of intestinal function, as well as less post-operative discomfort and a faster return to normal activities. However, these studies include little comparative data on patients treated by open appendicectomy.

Recently, both prospective and retrospective comparisons of the two approaches have been reported. Prospective studies (summarised in Table 10) have reached different conclusions concerning the relative effectiveness of laparoscopic and open appendicectomy. Attwood et al. found that the laparoscopic approach is superior to the open approach in terms of hospital stay, complications and return to normal activities.[57] On the other hand, Tate et al. found no significant differences in post-operative analgesic requirements, complication rates, hospital stays or return to work, although operating time for the laparoscopic approach was longer.[58] Kum et al. found no significant differences in operating times and length of hospital stays, but in their series return to normal activities was faster and wound infections less when the laparoscopic approach was used.[59] McAnena et al. did find differences between the two approaches in post-operative stays and wound infection, but not in use of analgesia, and suggest that the laparoscopic approach for acute appendicitis should be investigated further.[60]

Hospital stays associated with appendicectomy are already short compared with other abdominal procedures, limiting the cost advantages of the laparoscopic approach as far as service providers are concerned. In 1991–92, the average length of stay in Victorian public hospitals and all New South Wales and South Australian hospitals was 4.9 days (State health authority hospital morbidity data). Potential savings in bed-day costs for laparoscopic appendicectomy in comparison with open appendicectomy range from none to $1,000, depending on hospital stays achieved when laparoscopic appendicectomy is in routine use. Operating room costs for laparoscopic appendicectomy are higher than those for open appendicectomy, due to the equipment and instruments needed. An American study reports the savings in bed costs of laparoscopic appendicectomy to be completely offset by higher operating room charges.[61] Costs will vary depending on the mix of disposable and reusable instruments used and the choice of surgical technique.

The financial costs per patient episode to service providers have been estimated for laparoscopic and open appendicectomy (Table 11). If reusable instruments and loop ligatures are used and the hospital stay for laparoscopic appendicectomy is assumed to be 1.9 days shorter than for open appendicectomy, laparoscopic appendicectomy costs $300 less to service providers. If, however, there is no significant difference between the two techniques in terms of hospital stay, then the laparoscopic approach will cost $250 more due to higher equipment and instrument costs and the occasional laparoscopic procedure that needs to be converted to open surgery. If disposable clip appliers or linear cutters are used as well, the cost rises a further $200 to $700. Schirmer et al reached similar conclusions, obtaining a hospital cost of US$5,899 for laparoscopic appendicectomy and US$5,220 for open appendicectomy.[62]

It is not yet clear whether the laparoscopic approach to appendicectomy will provide greater benefit to patients and the community in comparison with open appendicectomy. Attwood et al. noted that patients returned to work or other activities significantly earlier following laparoscopic appendicectomy (10 days compared with 16 days) and had fewer post-operative complications.[57] On the other hand, Tate et al. found that similar proportions of patients had returned to work three weeks post-operatively.[58] They also noted that, while wound complications and wound pain post-discharge were less common following laparoscopic appendicectomy, the difference was not significant. Given the lack of good data to indicate otherwise, it would appear difficult at this stage to justify the use of laparoscopic appendicectomy over the open approach on the basis of a faster return to work or other activities.

Table 10: *Selected prospective studies comparing laparoscopic and open appendicectomy*

Characteristics	Attwood et al. (1992)	McAnena et al. (1992)	Tate et al. (1993)	Kum et al. (1993)	Mompean et al. (1994)
Method of sample selection	Random	Random when possible	Random	Random[a]	n.a.
Sample size:					
laparoscopic	30	27	70	57	100
open	32	36	70	52	100
Mean age of sample (years):					
laparoscopic	20.8 [b]	18	31.4	33.1	30
open	26.8 [b]	24	33.0	30.7	26
Average hospital stay (days):					
laparoscopic	2.5	2.2	3.5	3.2	4.8
open	3.8	4.8	3.6	4.2	6.0
Average time to return to work (days):					
laparoscopic	10	n.a.	(c)	19	n.a.
open	16	n.a.	(c)	32	n.a.
Median operation time (minutes):					
laparoscopic	61	48	70.3 [d]	43.4	51
open	51	52	46.5 [d]	40.1	46
Laparoscopic procedures converted to open (%)	6.7	0	20.0	0	5.0
Complication rates (%):					
Wound infection: laparoscopic	0	4	15 [e]	0	1
open	3	11	24 [e]	9	7
Other: laparoscopic	0	n.a.	10	0	8
open	9	n.a.	10	0	6
Mortality: laparoscopic	0	0	0	0	0
open	0	0	0	0	0

n.a. Not available

(a) Some patients excluded from each arm for clinical reasons, such as normal or perforated appendix discovered on operation

(b) Median, not average

(c) At an average follow-up time of 22–23 days post-operatively, similar proportions of laparoscopic and open patients had returned to normal activities.

(d) Average, not median

(e) As determined at follow-up consultation after discharge: n = 46 for laparoscopic and 42 for open patients

Source: References 57–60, 63

Table 11: *Summary of cost estimates [(a)] per patient episode of different procedures*

Item	Appendicectomy		Hernia repair		Vagotomy	
	open	laparo-scopic	open	laparo-scopic	open	laparo-scopic
Specialists' fees	362	380	372	371	719	719
Equipment and instrument costs	–	84	–	354	–	464
Hospital costs	1,847	1,131	1,508	1,131	5,730	1,885
Cost of conversion to open operation	–	148	–	56	–	799
Total	**2,210**	**1,743**	**2,069**	**1,912**	**6,450**	**3,868**

(a) Assumptions made in deriving costs and source of the data are detailed in Appendix 3.

The information available suggests that laparoscopic appendicectomy can be a safe and effective treatment for acute appendicitis. Whether it offers significant advantages over more traditional approaches, particularly in economic terms, needs further investigation through randomised trials.

Vagotomy

The potential use of laparoscopic vagotomy has to be set in the context of other available treatments for ulcers. Following their introduction in the late 1970s, histamine H_2-receptor antagonists have virtually replaced elective surgery in the treatment of intractable ulcer pain. H_2 antagonists such as cimetidine, ranitidine and nizatidine have proven to be safe and efficacious therapies for gastric and duodenal ulcers.[64] Side effects include central nervous system effects such as headaches, lethargy, confusion and depression, and occur in less than 3% of patients. A new drug, omeprazole, has recently emerged. This is an H^+/K^+-ATPase (proton pump) inhibitor and appears safe and efficacious in short-term therapy.[64]

Approximately 90% to 95% of gastroduodenal ulcers heal after eight to twelve weeks of drug therapy.[64] If treatment is discontinued, ulcers recur in 50% to 80% of patients within a year, placing them at risk of hemorrhage, perforation or obstruction. Long-term strategies are intermittent full-dose treatment when ulcer symptoms recur or a lower maintenance dose to reduce the recurrence rate. Recurrence rates are 75% to 100% after one to two years of intermittent treatment, and 10% to 32% after three to five years of maintenance therapy.[65]

Despite the widespread use of drug therapy in the last fifteen years, overall mortality rates associated with ulcers has not decreased over this time and may, in fact, be rising.[66,67] Reasons suggested include the use of non-steroidal anti-inflammatory drugs (NSAIDs) to alleviate other conditions in the elderly, reduced use of surgery since the introduction of H_2 antagonists, factors associated with social status, and ineffective use of medical and surgical therapies, especially in the elderly.

Recently, the bacterium *Helicobacter pylori* has been suggested as a factor in the pathogenesis of ulcers. Eradication of *H. pylori* has been found to significantly reduce the rate of recurrence of duodenal ulcers for up to seven years, with an ulcer recurrence rate of 3% in *H. pylori*-negative patients, compared with 20% in *H. pylori*-positive patients.[68] Combination therapies consisting of two antibiotics and often a site protective agent such as a bismuth compound have been used to eradicate *H. pylori* and reduce duodenal ulcer recurrence.[69,70] Difficulties with such therapy are the rapid development of antibiotic resistance by *H. pylori*, poor compliance, the complicated nature of the therapy, and side effects such as nausea, diarrhoea and hypersensitivity reactions occurring in up to one-third of patients.[69,71] *H. pylori* eradication may offer a

'cure' for some ulcer patients, but Peterson considers that large-scale prospective randomised trials that compare it with maintenance antisecretory therapy are needed.[71]

Surgical treatment is an option for patients with ulcers resistant to drug therapy or for those who do not comply with drug therapy. Surgical intervention may be necessary following the life-threatening complications of ulcers, hemorrhage, perforation or obstruction.

Surgical interventions include removal of part of the stomach (subtotal gastrectomy or pyloric antrectomy), vagotomy (division of the vagus nerves) and drainage (usually pyloroplasty, sometimes gastroenterostomy). Vagotomy can be truncal (the main vagus nerves are divided), selective (only gastric branches of the vagus nerve are divided) or highly selective (only some gastric branches are divided).

Truncal vagotomy with pyloroplasty has a low mortality rate (about 1%) and an ulcer recurrence rate over five years of less than 10% in most studies.[72,73] Complications can be significant, at rates of 11% to 12% for dumping syndrome and 20% for diarrhoea. Truncal vagotomy with anterectomy or a drainage procedure have mortality rates of 0.6% to 1.8% and recurrence rates of 1% to 2% and 5% to 15% respectively, with side effects occurring in 13% to 29% of patients.[74]

Selective vagotomy with pyloroplasty has similar recurrence and complication rates similar to truncal vagotomy with a drainage procedure, and is technically more difficult.[74] Highly selective vagotomy (proximal gastric vagotomy or parietal cell vagotomy) avoids the need for a drainage procedure, although better results are claimed by some if a drainage procedure is also performed.[75] Mortality is reported to be 0.2 to 0.3%, dumping and diarrhoea reduced to 1% to 2%, and recurrence is 9% to 18%.[66,72,74,75] A rare complication of necrosis of part of the stomach is fatal in half of all cases in which it occurs. An alternative, anterior seromyotomy and posterior truncal vagotomy, appears to have similar results, with mortality of 0.2% reported.[66] Another alternative, anterior highly selective vagotomy with posterior truncal vagotomy, takes longer to perform and does not appear to be as effective.

Laparoscopic and thoracoscopic vagotomies with pyloric stretch have been performed. These procedures will presumably be subject to complications similar to the equivalent open procedure (in addition to those of laparoscopy itself), and the effectiveness of the pyloric stretch technique is not known. Cuschieri has commented that truncal vagotomy with pyloric stretch

> 'has to be considered an untested treatment that requires adequate prospective long-term validation: it cannot be regarded as the endoscopic equivalent of any of the established antiulcer operations.'[76]

The laparoscopic version of posterior truncal vagotomy and anterior seromyotomy reproduces the essential steps of the equivalent open operation. Preliminary results indicate similar results to the open technique, with a shorter hospital stay.[76] However, only case reports and very small studies are available to date.

Laparoscopic highly selective vagotomy has been performed in Australia. It is likely to become the laparoscopic norm and the treatment of choice for elective duodenal ulcer surgery (Fletcher, personal communication). Laparoscopic repair of perforated ulcers has also been performed.

The safety and efficacy of the different forms of laparoscopic and thoracoscopic vagotomy are yet to be proven. Nor is it clear which of the different approaches available is the most effective. Fletcher has suggested that, with the exceptional view obtained laparoscopically, vagotomy performed by experienced laparoscopic surgeons may give much better results than open vagotomy (Fletcher, personal communication). McGuire and Schubert have suggested that laparoscopic vagotomy should initially be restricted to carefully controlled prospective randomised trials in which patients are followed for at least five years.[77]

Open vagotomy is typically associated with long hospital stays of 15 days (State health authority hospital morbidity data). However, such long stays are in most cases

associated with bleeding or perforated ulcers (Hugh, Jamieson, personal communications). After uncomplicated elective open vagotomy, hospital stays of five to six days are more likely. Consequently, the difference of $2,600 in direct costs to service providers between laparoscopic and open vagotomy (Table 11) may not be as significant in practice. A small proportion of vagotomies are likely to continue to be performed on bleeding or perforated ulcers and hence be associated with long hospital stays and high costs. The cost differential between open and laparoscopic vagotomy performed in other instances will be less.

If laparoscopic vagotomy proves to be safe and effective, the question of whether it might replace some medical therapy arises. Jensen has suggested that, for most patients with chronic uncomplicated peptic ulcer disease, open surgery will not be as cost-effective in terms of direct costs as long-term maintenance therapy for up to eight years, although surgery should be considered for patients in whom drug therapy fails due to complications or chronic recurrent disease.[78]

In Australia, medical therapy for ulcers represents a significant cost to the health care system. H_2 antagonists are commonly used to treat ulcers, with omeprazole reserved for those ulcers not responding to other drugs. The long-term ulcer sufferer on maintenance H_2 antagonist therapy at present uses approximately $210 of drugs annually. An additional cost is that of ongoing consultations. Some patients are on such medication only for acute episodes, which have an overall cost of up to $65 an episode at present. The cost to the Pharmaceutical Benefits Scheme in 1992–93 of drugs used to treat ulcers and reflux problems was $116,573,977 for H_2 antagonists and $18,280,003 for proton pump inhibiters (Commonwealth Department of Human Services and Health).

Medical therapy has replaced surgery for ulcers in Australia over the past fifteen years. From 1980–81, when H_2 antagonists were introduced to Australia, to 1991–92, the number of Pharmaceutical Benefits Scheme prescriptions for H_2 antagonists has risen to almost 2.5 million annually.[79] Over the same period, the number of Medicare Benefits rebates paid for vagotomy has fallen from approximately 1,500 to 340. If laparoscopic vagotomy does reduce the cost of surgical treatment of ulcers substantially, it may be a more attractive alternative to open vagotomy and compete with some of the medical therapy currently used. Whether laparoscopic vagotomy will be an alternative to currently used open surgical techniques or eventually replace some medical treatment remains to be seen, particularly since the role of *H. pylori* eradication therapy has not yet been determined.

Hernia repair

The most common types of hernia are inguinal and femoral (groin) hernias. Of all inguinal hernia repairs, 91% are performed on men, and 74% of femoral hernia repairs are performed on women.[80] Hiatus hernia is the most common form of diaphragmatic hernia, with gastroesophageal reflux commonly associated with it. Congenital diaphragmatic hernias occur in 2.8 per 10,000 births.[81] Other types of hernias include umbilical, lumbar, sciatic, epigastric and incisional, and occur less frequently.

Repair of a hernia is referred to as herniorrhaphy or hernioplasty. Early techniques involve repairing the hernia defect by sutures, with a number of variations of technique (including those by Bassini and Shouldice). An alternative approach, popularised by Lichtenstein, involves suturing a polypropylene mesh plug into the defect. Several preperitoneal approaches (i.e. viewing the inguinal wall from a posterior rather than anterior aspect) to inguinal hernias using a prosthesis (or plug) have also emerged.[82]

In the early 1980s a national study in the USA determined that at least 10% of all primary hernia repairs fail.[83] Approximately 40% to 50% of recurrences appear five or more years after the original operations, with 20% being discovered 15 or more years post-operatively. Rates reported by individuals or institutions generally appear better, due in part to inadequate length of follow-up and higher recurrence rates in patients

lost to follow-up. Recurrence rates of 3% to 23% have been reported by individual studies using Bassini's repair, of 0.2% to 11% using the Shouldice technique, and 1% to 11% for other techniques.[14,84] Proponents of approaches using prostheses, whether with the Lichtenstein or with preperitoneal techniques, claim lower recurrence rates due to the tension-free repair, but large series confirming these results are yet to be undertaken.[82,83] Recurrence rates of 0% to 13% have been reported by individual studies using these techniques.[82,84]

Operative complications of groin hernia repair include hemorrhage, visceral injury and severance of the vas deferens, nerves or testicular blood supply.[85] Post-operative complications include infection, hematoma, urinary retention, hydrocele, compression of the femoral vein, testicular atrophy and neuritis.[85,86] Reported mortality rates in the USA are 0.04% following repair of inguinal hernia, and 0.35%, 0.24%, 0.3% and 2.2% following repair of ventral, umbilical, femoral, and other or unspecified abdominal hernias respectively.[86,87] Mortality is higher in patients presenting with complicated hernias. Complication rates of 16.9% to 22.0% were recorded in a Victorian study.[88] Systemic and local complication rates of 0.5% to 6.9% and 1.2% to 8.7% respectively have been reported.[85,86,89]

Most laparoscopic approaches to repair of groin hernias involve insertion of prosthetic material over the inner aspect of the hernia defect, a modification of the preperitoneal open technique already described. One difference is that in the open technique the mesh is placed extraperitoneally, avoiding the risk of intestinal adhesions. In one laparoscopic version the mesh is placed intraperitoneally to cover all possible inguinal and femoral defects. Other versions place the mesh extraperitoneally. In developing the laparoscopic techniques, secure and accurate placement of a large prosthesis has been a problem.[90] Stapling the prosthesis with specially designed disposable instruments is easier than suturing, but introduces a new risk, that of driving the staples into underlying structures such as vessels or nerves.

From the scanty published data on laparoscopic hernia repair, the technique does not appear unsafe (Table 12), and is claimed to have a low overall complication rate by some.[91] General anesthesia is necessary, whereas it can often be avoided in open hernia repair.[90] Laparoscopy itself introduces additional risks to the patient. Some of the complications reported for laparoscopic hernia repair, such as lost foreign body, injury to the lateral cutaneous nerve of the thigh, and mesh-related small bowel obstruction, are specific to the laparoscopic approach.[90]

Other complications include damage to the bladder, bowel, vas deferens, osteitis pubis and iliac vessels, and testicular swelling and pain. Hugh comments that the 2.8% rate of neurological problems reported at a recent seminar are a cause of considerable concern.[90] Another concern is the possibility of adhesions and intestinal obstruction if the mesh is placed intraperitoneally instead of extraperitoneally as is usual in open methods. Mesh complications (migration and infection) can occur, with infection rates in open procedures of 2% to 10% reported.[92] A disadvantage of early laparoscopic techniques is that the peritoneal cavity is entered, which did not occur with more traditional techniques. However, a balloon dilatation device has been developed that allows preperitoneal access without entering the peritoneal cavity.

A report of an Australian series (of 232 cases) performed at a teaching hospital presents some alarming results. In 6.9% of cases the laparoscopic approach was abandoned.[93] Bladder injury occurred in 1.3% and adhesive bowel obstruction in 0.5% of cases, all requiring open surgery. Of the 2.3% of cases suffering from post-operative nerve injury, 0.5% also required subsequent open surgery. Other complications included incisional hernia, wound infection or hematoma, urinary tract infection and hydrocele. The recurrence rate in a subgroup of these patients was 22%.

Table 12: *Selected prospective studies [a] of laparoscopic hernia repair*

Characteristics	Sailors et al. (1993)	Winchester et al. (1993)	Hawasli (1992)	Dion & Morin (1992)	Arregui et al. (1993)	Goodall (1994)
Sample size	48	38	125	10	122	60
Mean age of sample (years)	55	52	55	44	48	55
Average hospital stay (days)	n.a.	3.2	n.a.	2 [b]	n.a.	1.3 [b]
Average time to return to work (days)	90 [c]	97 [c]	7–14	n.a.	n.a.	14
Mean operation time (minutes)	70 [d]	90	70 [d]	n.a.	n.a.	56
Laparoscopic procedures converted to open (%)	4.2	n.a.	n.a.	n.a.	1.6	5.0
Complication rates (%):		23.7			8.2	
major	37.5	n.a.	9.8	0	n.a.	0
minor	4.2	n.a.	1.4	0	n.a.	10
Number of patients with bilateral hernias	15	2	14	n.a.	22	12
Mortality (%)	0	0	0	0	0	0
Recurrence rate (%)	0	0	1.6	n.a.	1.6	1.7
Mean follow-up (months)	5.8	5.5	n.a.	n.a.	n.a.	n.a.

n.a. Not available

(a) All studies were non-randomised.

(b) Post-operatively

(c) Percentage returned to work one week post-operatively.

(d) For unilateral hernia repairs. Bilateral repairs were longer.

Source: References 92, 94–98

Advantages claimed for the laparoscopic approach are reduced post-operative pain, faster return to work, no muscle incision, and recognition and subsequent early repair of an unsuspected contralateral hernia.[92,98] However, data supporting these claims are at present sparse. Early results give promising recurrence rates of 3% or less (Table 10),[90] but larger studies with long follow-up are lacking. Hugh concludes:

> 'the differences in outcome between modern, open, day-case hernia repair done under local anaesthesia, and laparoscopic herniorrhaphy are by no means as clear-cut and obvious as in the case of laparoscopic versus open cholecystectomy, and unless meticulous trials are carried out the issue will remain undecided for many years.'[90]

Even those who consider laparoscopic inguinal hernia repair to be safe and effective have noted that the procedure is in transition and needs to be studied carefully, especially in regard to long-term recurrence rates.[91] A recent audit of laparoscopic herniorrhaphy undertaken in Western Australia under the auspices of the RACS concluded that laparoscopic hernia repair should be performed only as part of controlled clinical trials.[99]

Laparoscopic hernia repair is still evolving, and the most appropriate technique for each type of groin hernia is still to be determined. Large controlled trials with long follow-up periods are needed to determine recurrence rates. Randomised controlled trials comparing laparoscopic hernia repair with standard open techniques are needed to assess the true benefit of the laparoscopic approach in terms of reducing post-operative pain and allowing an earlier return to work or normal activities. In view of its additional and potentially serious complications and recent reports of high complication rates, the relative safety of the laparoscopic approach in comparison with more traditional approaches needs further evaluation.

Costs

In a large study of US Army experience in the early 1980s, an average hospital stay of 4.6 days was reported following inguinal hernia repair.[87] Smaller and more recent studies report shorter stays, including less than 24 hours.[86] A 1988 Victorian study noted an average length of stay of 3.9 days associated with hernia repair in a district hospital as compared with 6.7 days in a central hospital.[88] Pre-operative stay was longer in the central hospital due to administrative problems, availability of operating time and admission for pre-operative investigations. In the post-operative period there was a significant difference in the two hospitals between the day of operation and the time the surgeon stated that the patient could be discharged, implying differences in surgical philosophy and practice.

Average lengths of stays in Australian hospitals for hernia repairs are about 4 days for inguinal hernias and longer for most other types of hernia (Table 13). Approximately 15% of hernia repairs performed in public hospitals in NSW and Victoria do not involve an overnight stay (State health authority hospital morbidity data).

Mean hospital stays for laparoscopic hernia repair are two to three days in series reported in the literature, although stays may be longer in routine clinical practice. With a hospital stay of three days, laparoscopic hernia repair, like laparoscopic appendicectomy, offers little cost advantage to service providers (Table 11). Again, the laparoscopic approach will be more costly if there is found to be no significant decrease in hospital stay compared with that for open repair, or if use of disposable instruments adds significantly to costs. If laparoscopic hernia repair is found to have higher complication or recurrence rates than open repair techniques, these will also add to the cost of the technique.

The time taken to return to work following open inguinal hernia repair has been recorded in the UK as 4.4 weeks for sedentary work to 8.3 weeks for heavy work.[100] The time patients are advised to take off work by surgeons is shorter. Surgeons advise 2.6 weeks off for sedentary work and 7.1 weeks off for heavy work. Robertson et al. have suggested that patients might be happy to return to work much faster than they

do if they were aware that it would have no detrimental effect.[100] Similar results might be expected in Australia, but local data could not be located during preparation of this report. Much shorter return periods have been recorded for laparoscopic hernia repair, with most patients returning to work within two weeks (Table 12). On the other hand, a US report states 95% of patients returned to their usual activities within a week of open plug repair of their hernias.[101]

The eventual role of laparoscopic hernia repair techniques as part of the range of available repair techniques is not yet clear. The number of hernia repairs performed annually has been increasing slowly in recent years (Table 2). Patients' perceptions of laparoscopic hernia repair as a less traumatic procedure than open alternatives has the potential to pressure for the replacement of open hernia repairs with laparoscopic techniques. Uncertainties about cost advantages as well as technical issues and safety highlight the need for further evaluation of laparoscopic hernia repair.

Table 13: *Average length of hospital stay (days) associated with hernia repair in New South Wales, Victoria and South Australia, 1991–92*

Type of hernia	NSW	Vic [(a)]	SA
Diaphragmatic	13.6[(b)]	22.0[(b)]	11.1[(b)]
Incisional	6.8	6.5	7.8
Umbilical	4.4	3.6	4.0
Inguinal	4.3	3.7	4.6
Femoral	5.8	6.1	6.8
Other	6.1	7.9	5.4
All	**4.7**	**4.3**	**4.9**

(a) Public hospitals only

(b) Small number of admissions

Source: State health authorities

Fundoplication

Gastroesophageal reflux occurs normally at times in most people and is usually asymptomatic, but where it occurs with abnormal frequency it becomes pathological. Gastroesophageal reflux can occur in association with hiatal hernia, although hiatal hernias by themselves are generally asymptomatic or cause only mild symptoms of epigastric fullness or distress. Potential complications of gastroesophageal reflux include stricture, esophagitis, hemorrhage, aspiration of gastric contents into the lung and respiratory problems.

Lifestyle changes such as modifying diet and avoiding certain drugs that may aggravate gastroesophageal reflux are useful for some patients. Others, including those with more severe disease, may benefit from medical therapy. This includes H_2 antagonists and proton pump inhibitors to decrease acid secretion, mucosal-coating drugs such as antacids and promotility agents which increase esophageal clearance and gastric emptying. Although many drugs provide symptomatic relief, only the H_2 antagonists and proton pump inhibitors have been conclusively shown to promote healing of esophageal mucosa.[102] Often higher dosage levels are needed than for peptic and duodenal ulcer therapy.[103]

Surgery may be indicated for patients with severe intractable symptoms or life-threatening complications, or for those not compliant with drug therapy. Nissen's fundoplication is the most common of three operations used to surgically treat reflux problems, the others being the Hill posterior gastropexy and the Besley Mark IV repair. Nissen's fundoplication gives relief of reflux symptoms over more than ten years in 91% of patients.[104] The procedure has a morbidity rate of 17% and a mortality rate of

1%.[105] Complications include gastroesophageal leak, injury to liver or spleen, esophageal obstruction, dysphagia, infection, hemorrhage and pulmonary complications such as atelactasis.[105]

Laparoscopic modification of the Hill posterior gastropexy procedure is likely to be difficult and possibly hazardous. A thoracoscopic approach to the Besley Mark IV procedure is theoretically possible. Laparoscopic fundoplication has been used in several small studies. Complications include emphysema, pneumothorax, dysphagia and thromboembolism.[106,107] Mortality rates reported are 0% to 1%. The laparoscopic approach reduces hospital stays from 8 to 3–4 days and return to work from six weeks to about a week (Jamieson, personal communication). However, the procedure has a very long learning curve and complications are very significant in a small proportion of patients. After three months follow-up of 100 patients, Jamieson has concluded that, while 87% were better off with the laparoscopic approach, 13% were disadvantaged by problems not normally occurring with the open procedure.[106]

Drug therapies for gastroesophageal reflux such as H_2 antagonists and proton pump inhibitors are expensive. As with vagotomy, laparoscopic fundoplication could potentially impact on drug therapy if concerns such as those relating to complications are solved. Similar questions to those raised by laparoscopic vagotomy remain unanswered.

Bowel resection

Laparoscopic (or laparoscopically assisted) bowel resection is at an early stage of development. Some early results are presented in Table 14. Advantages of the laparoscopic approach to bowel resection reported include an earlier return to bowel function, reduced post-operative pain and earlier discharge from hospital than following an open approach.[108,109]

Table 14: *Selected prospective studies of laparoscopic bowel resection*

Characteristics	Phillips et al. (1992)	Monson et al. (1992)	Scoggin et al. (1993)	Peters & Bartels (1993)	Wexner et al. (1993)
Method of sample selection	n.a.	Consecutive	Clinical[a]	Clinical	n.a.
Sample size	51	40	20	28	74
Mean age of sample (years)	n.a.	69[b]	72	66	45
Average hospital stay (days)	4.6	8[c]	5[b,c]	4.8	7.0[b]
Average time to return to work (days)	n.a.	n.a.	n.a.	n.a.	n.a.
Mean operation time (minutes)	138	210–240[d]	178	n.a.	180[b]
Laparoscopic procedures converted to open (%)	7.8	17.5	n.a.	14.3	4.1
Complication rate (%)	7.8	21.2	20.0	14.3	33.8
Mortality (%)	2.0	2.5	0	3.4	0

n.a. Not available

(a) Includes some polypectomies and colostomies

(b) Median, not mean

(c) Post-operative stay only

(d) Depending on type of resection

Source: References 109–113

Complications included ileus, arterial injury, cerebrovascular accidents, urinary retention, hemorrhage and infection. Other potential difficulties are a higher rate of anastomosis leaks compared with open procedures, the possibility of tumour spillage or crushing tumour cells into the staple line, and a higher rate of ureteral injuries (especially early in a surgeon's experience) compared with open procedures.[8,9,114] Trocar port recurrences have been reported after carcinoma resection, and local recurrence rates are unknown at this stage.[9]

Laparoscopic bowel resection is technically more difficult than procedures such as laparoscopic cholecystectomy and operation times are much longer. Considerable skill and training is needed, and the learning curve is, in O'Rourke and Heald's words 'daunting'.[9] Wexner et al. have concluded that no advantages of laparoscopic colonic and rectal procedures over open procedures can be substantiated to date.[111] Larger comparative studies with open alternatives are needed to establish the safety and efficacy of laparoscopic bowel resection and its role in treatment of colonic disease. A prospective register of all patients has been suggested, to avoid under-reporting of mishaps.[9]

Urology

A number of urological procedures have been performed using the laparoscopic approach. Laparoscopy has been used to locate non-palpable testis for some years and is a safe and reliable method for doing so.[115-117]

Several smaller studies of laparoscopic pelvic lymphadenectomy for staging prostatic cancer have been published, and results appear similar to those for the alternative open technique.[115,117,118] However, opinions differ as to the application of this technique, with Boullier and Parra considering it the staging procedure of choice before both radical perineal and retropubic prostatectomy, but Clayman and Kavoussi considering that its use before radical retropubic prostatectomy should be limited.[115,118] Other concerns that need to be addressed include recent reports of untoward morbidity and the possibility of intra-abdominal seeding of tumour cells.

Varicoceles are more common in subfertile than in fertile men. Methods of treatment include open varicocelectomy and transvenous embolisation of the spermatic vein, and a laparoscopic approach to varicocelectomy. Open varicocelectomy can be performed through small incisions and transvenous embolisation requires only a local anesthesia. Consequently, advantages of the laparoscopic technique over alternatives are not clear-cut and require further investigation.[115,117]

Other laparoscopic procedures that have been used in urology include ureterolysis, nephrectomy, bladder suspension (for stress incontinence), adrenalectomy, nephroureterectomy, prostatectomy and ureterolithotomy. To date, each has been performed in a small number of patients, and many can be expected to evolve with further developments in instrumentation and techniques.

One disadvantage of laparoscopic surgery for the urologist is that the organs of interest are extraperitoneal. Until recent development of a balloon device to dilate the retroperitoneum, use of the laparoscope has meant that the peritoneal cavity needed to be entered first, and then the surgical field accessed from a different viewpoint than that used with an extraperitoneal approach.[119] Diffusion of laparoscopic techniques has been slower in urology than in general surgery because of such access difficulties, lack of instruments specifically designed for these procedures, and the longer time taken in comparison with open operations.

Diagnostic laparoscopy

Laparoscopy has been used since the turn of the century by gynecologists and gastroenterologists as a diagnostic tool. Its use in gynecology is widespread, as Table 15 illustrates. In gastroenterology and general surgery its use is less common and was

supplanted to a large extent in the 1980s by imaging tests such as CT scanning, ultrasonography and magnetic resonance imaging (MRI). These technologies allow image-guided biopsies to be performed and have the advantage of being non-invasive.

Interest in the use of diagnostic laparoscopy in abdominal disorders has returned. It is seen as being a safe and accurate diagnostic tool that is complementary to other diagnostic modalities.[120-122] Laparoscopically guided biopsies have a number of advantages. There is improved access to areas not easily reached by percutaneous or radiologically guided biopsy, obviously diseased areas are sampled due to visual control, multiple biopsy specimens can be taken and better hemostasis is obtained than with percutaneous liver biopsy.[120]

A significant use suggested for diagnostic laparoscopy is in the staging of neoplastic diseases, where it might avoid additional CT scans or unnecessary surgery in some patients.[120,121,123] One study reports laparoscopy to be superior to ultrasound or CT scanning in determining the presence of liver and peritoneal metastases, and to ultrasound but not CT scanning with regard to nodal metastases.[124] Intraoperative sonography is considered by some to be superior to conventional ultrasonography, CT and MRI in the diagnosis of gastrointestinal malignancies and in localising lymph node and hepatic metastases.[123,125] It has recently been combined with laparoscopy with a view to overcoming the disadvantages of both laparoscopy alone and conventional scanning techniques.[125] Another recent development is the use of an optical catheter in conjunction with laparoscopy and biopsy to evaluate intraperitoneal malignancies.[126]

Diagnostic laparoscopy has been used to evaluate chronic pelvic pain in women for some time. Where appendicitis or adhesions appear to be the cause of pain, therapeutic measures can be taken laparoscopically within the same procedure. Laparoscopy can reduce the negative appendicectomy rate, but there are still false positive and false negative diagnoses, on the basis of comparison with histopathology.[60] Laparoscopy might be useful in diagnosing other causes of acute abdominal and pelvic pain such as acute diverticulitis, perforated peptic ulcer, acute cholecystitis, acute gynecological conditions and mesenteric infarction.[127]

As well as staging neoplastic diseases and evaluating abdominal and pelvic pain, diagnostic laparoscopy has been suggested as a useful assessment technique in liver diseases such as cirrhosis, ascites, intrahepatic cysts and hepatomegaly.[120,122] Laparoscopic ultrasonography might be useful in assessment of the common bile duct.[125] Diagnostic laparoscopy has been suggested as an adjunct to scanning techniques in the evaluation of abdominal masses and fever of unknown origin.[120] It has been used in trauma patients and found to have advantages over alternatives such a diagnostic peritoneal lavage in patients with stab and gunshot wounds, but not in blunt trauma.[128,129]

Laparoscopy has an emerging role in the diagnostic area complementary to conventional scanning techniques. Its use to evaluate chronic pelvic pain in women is well established, but further information is needed about its accuracy in other diagnoses in comparison with conventional scanning. However, the fact that it is more invasive than scanning techniques should not be forgotten. Potential complications include cardiac arrhythmias and needle and trocar injuries; deaths have been reported.[130]

Table 15: *Number of services attracting payments from the Medical Benefits Schedule for selected endoscopic and surgical procedures by year*

Type of procedure	Current item no.	1986–87	1987–88	1988–89	1989–90	1990–91	1991–92	1992–93
General								
Diagnostic laparoscopy	30390	18,924	17,024	16,716	16,072	16,454	16,721	16,751
Laparoscopy with biopsy	30391	358	403	254	307	276	424	444
Gastrointestinal tract								
Diagnostic esophagoscopy	41816	1,191	1,147	1,124	1,136	1,160	1,187	1,267
Esophagoscopy for biopsy, dilation or insertion of prothesis, removal of foreign body	41819 to 41825	4,758	5,332	5,809	6,486	6,759	7,100	6,768
Arthroscopy								
Diagnostic arthroscopy of knee	49557	8,210	7,797	7,042	6,926	6,967	6,831	6,730
Arthroscopic surgery on knee	49560 to 49566	–	–	–	–	–	17,003[a]	37,049
Other operations on knee	49500 to 49554	26,157	27,644	28,470	33,313	37,391	28,528	13,937
Diagnostic arthroscopy of shoulder	48945	–	–	–	–	–	168[a]	421
Arthroscopic surgery on shoulder	48948 to 48960	–	–	–	–	–	917[a]	2,324
Other operations on shoulder	48900 to 48942	–	–	–	–	–	1,579[a]	3,581
Diagnostic arthroscopy of elbow	49118	–	–	–	–	–	43[a]	92
Arthroscopic surgery on elbow	49121	–	–	–	–	–	131[a]	276
Other operations on elbow	49100 to 49115	–	–	–	–	–	315[a]	663
Diagnostic arthroscopy of wrist	49218	–	–	–	–	–	33[a]	87
Arthroscopic surgery on wrist	49221 to 49227	–	–	–	–	–	153[a]	413
Other operations on wrist	49200 to 49215	–	–	–	–	–	203[a]	455
Diagnostic arthroscopy of ankle	49700	–	–	–	–	–	76[a]	156
Arthroscopic surgery on ankle	49703	–	–	–	–	–	319[a]	951
Other operations on ankle	49706 to 49727	–	–	–	–	–	1,051[a]	2,512
Diagnostic arthroscopy of other joints	50100	–	–	–	–	–	34[a]	64
Operations on hip	49303 to 49345	–	–	–	–	–	3,634[a]	8,369
Diagnostic arthroscopy on shoulder, elbow, wrist, hip or ankle	8072 [b]	–	–	292	425	436	276	–
Operations on shoulder, elbow, wrist, hip or ankle	8009 to 8019, 8036 to 8070, 8074, 8113, 8116, 8290 [b]	14,982	16,995	17,881	19,435	21,172	12,640	83

Table 15 (continued): *Number of services attracting payments from the Medical Benefits Schedule for selected endoscopic and surgical procedures by year*

Type of procedure	Current item no	1986–87	1987–88	1988–89	1989–90	1990–91	1991–92	1992–93
Thoracic								
Thoracoscopy, with or without division of adhesions	38436	65	56	87	117	113	115	215
Percutaneous needle biopsy of lung	38412	–	–	–	455	681	686	730
Gynecology								
Laparoscopy for treatment of cysts, endometriosis, adhesions and other procedures	35637	23,411	24,075	25,024	25,345	25,318	25,450	24,834
Complicated operative laparoscopy	35638	–	–	–	–	–	537(a)	4,211
Sterilisation by transection or resection of Fallopian tubes by abdominal or vaginal routes of laparoscopy	35687, 35688	24,875	20,978	19,519	17,737	14,215	13,311	12,236
Hysteroscopy for biopsy or other diagnosis, curettage, adhesiolysis, polypectomy, tubal catheterisation or removal of IUD	35626 to 35633	1,184	1,920	2,904	7,269	17,742	23,457	26,859
Curettage of uterus with or without dilatation	35639, 35640	107,141	105,658	103,792	97,137	90,774	86,532	72,225
Urology								
Ureteroscopy for stone removal or destruction, biopsy or diathermy	36806, 36809	548	697	791	798	888	1,027	1,037
Other ureteroscopy	36803	275	331	351	412	440	534	546

(a) Data from November 1991.

(b) Item numbers prior to November 1991; subsequently replaced by items relating to individual joints.

Source: Health Insurance Commission, Commonwealth Department of Human Services and Health

Other procedures

Arthroscopic surgery

Arthroscopic surgery has been routinely performed on the knee for some years. Over this time the number of operations on the knee has increased dramatically; between 1986–87 and 1992–93 there was a 95% increase in Medicare Benefits payments for knee surgery (Table 15). One reason is that the lesser morbidity of arthroscopic over open surgery has led to treatment of problems that might otherwise not been treated surgically.[131]

As instrumentation and techniques have improved, arthroscopic surgery has extended to other joints. Arthroscopic surgery on joints such as the wrist, shoulder and ankle has attracted a Medicare rebate since late 1991, but use of these procedures is still quite limited in comparison with arthroscopic knee surgery (Table 15). Medicare Benefits payments for diagnostic arthroscopy of these joints have doubled between 1989–90 and 1992–93. However, levels of Medicare Benefits payments for joint surgery overall appear to be relatively constant. Operative techniques in arthrosopy continue to evolve. Controlled studies are needed to establish the clinical efficacy of the numerous arthroscopic procedures already developed, and to determine if arthroscopic techniques can improve the long-term outcome of degenerative joint disease.

Hysteroscopic surgery

Menorrhagia (excessive menstrual bleeding) is a common condition in women in their reproductive years. It has been estimated to occur in 9% to 14% of healthy women, and to be the main reason for 5,300 hysterectomies annually.[44,132]

The hysteroscopic techniques of endometrial resection or ablation have been developed as alternatives to hysterectomy for this condition. Not needing any incision, they are considerably less traumatic than traditional forms of hysterectomy. Patients are usually discharged within three days of operation, and some can be discharged the day of operation.[44] Many patients have returned to normal activities within two to three weeks.

Endometrial resection/ablation has been diffusing into general clinical practice over the past three or four years. In terms of Medicare Benefits payments made, endometrial resection/ablation appears to have been performed in addition to hysterectomy rather than replacing it (Table 16). However, some impact on hysterectomy rates is evident if hospital morbidity data are examined (Table 17). In New South Wales endometrial resection/ablation had made a considerable impact on hysterectomies performed for menorrhagia by 1991–92. In Victoria the impact was less marked and might in part be due to normal annual variations. In South Australia no effect is discernible at this time. These data would suggest that there can be significant differences between States in the timing of introduction and diffusion of new MAS techniques.

It is not entirely clear from the available data whether endometrial resection/ablation is replacing hysterectomies or whether some additional surgery is being performed. The latter is a distinct possibility in some instances. Menorrhagia is a complaint diagnosed on the basis of subjective evidence. Medical management is available, but is not effective in all instances, is generally not effective once the drug is ceased and is associated with side effects. On the other hand, hysterectomy is a major surgical procedure with a long recovery period which, although it might solve some problems, can create others, such as the need for hormone replacement therapy or a higher risk of cardiovascular disease.[44]

It is possible that some who tolerated this condition or the side effects of a medical regime rather than undergo hysterectomy might choose to go through a much less invasive procedure that has a good chance of lessening or curing their condition. If so, an increased surgical caseload for the treatment of menorrhagia would result. It is also possible that, in the next few years, the situation may change again. A new medical therapy, the levonorgestrel intrauterine device (Lng IUD), offers the promise of being effective in reducing menstrual blood loss with few side effects and might become the first line of treatment for menorrhagia, leaving surgery as an option if it fails.[133] It certainly appears that LAH is unlikely to compete with endometrial resection/ablation in the surgical treatment of menorrhagia, although it might replace abdominal hysterectomies performed for other reasons.

Table 16: *Number of Medicare Benefits payments for endometrial resection/ablation and hysterectomy by year*

Year	Endometrial resection/ablation	Hysterectomy (all forms)	Total
1987–88	–	20,968	20,968
1988–89	–	20,590	20,590
1989–90	–	20,408	20,408
1990–91	2,349(a)	19,719	22,068
1991–92	4,433	19,920	24,353
1992–93	4,723	20,362	25,085

(a) Includes data for June 1990

Source: Health Insurance Commission, Commonwealth Department of Human Services and Health

Table 17: *Hysterectomies performed with a principal diagnosis of menorrhagia for 1988–89 and 1991–92 by State*

State	Number of hysterectomies performed 1988–89	1991–92	Percentage decrease
New South Wales	1,432	936	35
Victoria(a)	482	401	17
South Australia	677	670	1

(a) In public hospitals only

Source: Reference 44

Thoracoscopic surgery

Thoracoscopy has been used for some time in diagnosis and to treat pleural adhesions. With recent developments in endoscopic equipment and surgical technique, the range of procedures able to be performed thoracoscopically has expanded. Newer thoracoscopic procedures include lung biopsies, resection of pulmonary metastases, management of pericardial and pleural effusions, cervical sympathectomy and implantation of an implantable cardiac defibrillator.

The major cause of morbidity in all thoracotomies, even limited and muscle-sparing procedures, is the incision and associated spreading of the ribs. Thoracoscopy provides access to the thoracic cavity by a less morbid approach, potentially reducing hospital stays and speeding recovery. Mack et al. comment that the thoracoscopic approach does not compromise the adequacy of the procedure and that procedures such as sympathectomy, pericardiectomy and blebectomy can be performed more simply and expeditiously thoracoscopically than by standard open techniques.[134] However, as in

many areas of laparoscopic surgery, large comparative studies of thoracoscopic and open alternatives are lacking.

In a small comparative study, Bensard et al. found that the thoracoscopic approach to lung biopsies reduced hospital stays (from 5.7 to 2.6 days), the time required for pleural drainage and the number of complications.[135] Diagnostic accuracy of biopsies obtained by the thoracoscopic and open approaches appeared similar. Thoracoscopic resection of localised nodules has been used therapeutically in a small number of cases, as well as a diagnostic tool that allows some patients to avoid thoracotomy.[136-138] However, McCormack et al. suggest that the inability to palpate the lung thoracoscopically raises the possibility of incomplete resections, and question the role of thoracoscopy for resection of metastatic tumours other than for confirmation of diagnosis.[139]

Upper thoracic sympathectomy has been performed thoracoscopically to treat hyperhidrosis and limited cases of vascular disorders, tachycardia and reflex sympathetic dystrophy.[140] Success rates for hyperhidrosis range from 70% to 100% in a number of small studies.[140-142]

Complications of thoracoscopic surgery include recurrent pneumothorax, hemorrhage, atelectasis, infection, acute myocardial infarction and respiratory failure.[135,138,140,143] Mortality rates of up to 1% have been reported.[136,143] As for laparoscopic surgery, some thoracoscopic procedures will need to be converted to open procedures.[135,136]

Although a number of procedures can be performed thoracoscopically, the future clinical use of some may be limited. For example, with the recent development of transvenous leads for implantable cardiac defibrillators, thoracoscopic implantation of these devices is likely to be limited to those cases where transvenous leads are contraindicated. Mack et al. have concluded that the thoracoscopic approach may become the preferred technique in lung biopsies, excision of cysts, blebectomy, wedge resection, sympathectomy, pericardiectomy and treatment of pneumothorax.[134] Its role in the management of problems such as spinal diseases, protruding discs, esophagomyotomy for achalasia, esophageal leiomyomas and trauma is yet to be determined.

In 1992 Lo Cicero commented:

> '. . . claims of superiority of this technology over traditional methods are premature. Unscientific preliminary reports presented in the news media and the lay press only heighten patient expectations and place undue pressure on the medical community to engage in an unproven but potentially very expensive and underdeveloped new technology. Careful, thoughtful comparative studies are necessary and exposure to the peer-review process of scientific meetings and journals is important in establishing the credibility of this new technology.'[144]

Since, in the main, only small non-comparative studies have appeared in the literature in the intervening time, these comments would still appear to be relevant.

Other issues

There are a number of general issues raised by the wider introduction and use of laparoscopic surgery, in addition to those relating to or arising from specific procedures which have already been covered. These matters include changes to standard practice, safety of the new procedures, training requirements, conversion to open procedure, use in day surgery, patient requirements, costs of surgery and changes in instrumentation and in institutional structure.

Changes to standard practice

Difficulty in performing all or part of a procedure laparoscopically may change standard surgical practice. In the case of laparoscopic cholecystectomy, operative cholangiography and exploration of the common bile duct are more difficult to perform laparoscopically than the cholecystectomy itself. A New Zealand survey of surgeons found that 72% had deliberately changed their policy with respect to the use of operative cholangiography when they changed from open to laparoscopic cholecystectomy, with operative cholangiograms now being used in only 7% of cases.[145]

In Australia between 1988–89 and 1991–92, the percentage of cholecystectomies performed laparoscopically that attracted Medicare Benefits payments has increased to 69% of all cholecystectomies. At the same time, the percentage of procedures where an operative cholangiogram was also performed that attracted Medicare Benefits payments has fallen from 87% to 23%.[146] Similarly, open exploration of the common bile duct has decreased by 46% but endoscopic treatment of common bile duct stones has increased by 242%.

Fletcher suggests that in half of the cholecystectomy patients no attempt is made to exclude common bile duct stones, and that the added risk of managing such stones in these patients is predicted to increase mortality from common bile duct stones 1–3-fold and morbidity 10–15-fold.[146] Windsor and Vokes suggest that every surgeon should consider performing operative cholangiography with laparoscopic cholecystectomies until sufficiently competent to perform it when required, after which the indications should be the same as when the surgeon performed open cholecystectomy.[145]

Cuschieri has commented that the laparoscopic technique of truncal vagotomy and pyloric stretch cannot be regarded as an endoscopic equivalent of the open procedure and needs to be evaluated as a completely new technique.[76] White has made similar comments about laparoscopic hernia repair, since the standard of care for open hernia repair was repair of the defect rather than a plug technique.[147] He points out the need for surgeons to decide, with each laparoscopic technique, whether it represents an extension of the surgeon's ability to perform the appropriate surgery necessary to treat the patient's disease, or whether the approach to the patient is being changed to accommodate unfamiliar instruments.

Safety

As well as complications specific to laparoscopy, longer term effects associated with laparoscopic surgery have occurred. Subcutaneous metastases at port sites have been reported following laparoscopic resection of (sometimes unsuspected) malignancy.[148,149] Incisional hernias have occurred at larger port sites.[150]

Higher rates of some serious complications following laparoscopic surgery are also of concern. While most patients benefit from the laparoscopic approach, some are disadvantaged. Judgement is needed on when the level of increase in major complication rates is no longer acceptable. The rates of long-term effects of such

injuries (for example, common bile duct injuries following laparoscopic cholecystectomy) on patients and the community need to be defined and such information made widely available.

Guidelines for credentialing groups of procedures have been suggested by Fletcher.[79] The first group are equivalent procedures, where the result of the laparoscopic procedure is exactly the same as for the open alternative (as with cholecystectomy). The second group are alternative procedures, where the laparoscopic procedure is new or different or there is some uncertainty of outcome (as with colon resection). These procedures clearly require assessment by clinical trial or audit.

The third group have been defined by Fletcher as indifferent procedures, ones in which existing surgical principles are not followed or there is no attempt to reproduce that which was achieved by open surgery. As an example, he cites laparoscopic truncal vagotomy and pyloric dilation being used instead of highly selective vagotomy. Using the criteria for performing a procedure laparoscopically (that the pathology be safely and effectively managed by this approach and that the major morbidity of the open alternative was the wound access), laparoscopic inguinal hernia repair falls into this category. Such laparoscopic procedures need to be shown to be safe and effective compared with alternatives in controlled trials.

The first group of procedures might be considered not to need to be rigorously shown to be safe and effective. However, an alternative view is that they still encompass significant changes to traditional surgical practice and consequently need to be validated through appropriate trials before becoming standard clinical practice.

Training

Adequate training for surgeons has been an issue since the introduction of laparoscopic cholecystectomy, especially since complications such as bile duct injury are more frequent early in a surgeon's experience. From the surgeon's point of view, disadvantages of the laparoscopic approach are lack of tactile input and ability to judge pathology by touch, the reduced ability to apply direct pressure to control bleeding or to retract powerfully to display tissue planes, and working through small windows as compared to an open technique.[9] Laparoscopic techniques have meant that surgeons have needed to acquire completely new skills. This has not necessarily been easy for all surgeons.[151] It is also difficult for rural surgeons in terms of costs and time away from their practice. A Bunbury surgeon has questioned whether further extension of surgical techniques is feasible for some.[152]

Determination of appropriate standards for training in laparoscopic surgery is a role of professional organisations. The Royal Australian College of Obstetricians and Gynaecologists (RACOG) has divided laparoscopic gynecological surgery into four levels of difficulty, from diagnostic procedures in level one to advanced surgery by acknowledged teachers in the field in level four. The RACOG notes numbers of supervised procedures to be performed at each level, and the minimum annual caseload needed to maintain expertise in a level. The RACOG comments:

> 'there will be a small group of gynaecological surgeons who may never learn the necessary skills to safely and effectively perform gynaecological endoscopic surgical procedures'.[153]

The question of a similar suitable gradation of difficulty in laparoscopic procedures for specialties such as pediatric and thoracic surgery has been raised in Canada.[154]

The RACS has issued training recommendations for laparoscopic cholecystectomy and a policy statement covering new technology and surgical practice. The RACS recommendations include ongoing audit of indications and outcomes of procedures performed by individual surgeons as well as participation in hospital, region or College-based audits of aggregated data.[155] Such participation in surgical audits is one of the requirements for recertification, which is to be introduced by the RACS in 1995 (RACS, personal communication).

One difficulty facing a surgeon is the lack of encouragement and sometimes opportunity to acquire and practise a full range of laparoscopic skills matching those from open surgery. For example, laparoscopic cholecystectomy uses a clip applier; surgeons did not need to learn to suture laparoscopically to perform this procedure.

Surgeons need to maintain as well as develop skills to perform individual laparoscopic procedures. Warshaw suggests that the surgeon performing one Nissen's fundoplication a year perhaps should not be performing even that one.[156]

Introduction of laparoscopic techniques has had effects on the training of new surgeons. To gain familiarity with the new laparoscopic techniques, senior surgeons in some instances have performed appendicectomies and other procedures on patients normally operated on by junior surgeons as part of their training.[57,157] Those training new surgeons are often learning the new techniques themselves. Trainees are now being exposed to a different range of procedures than in the past, and may be less experienced in the performance of open procedures (RACS, personal communication).

The role of hospitals in relation to training is to ensure that their surgeons have met the training standards set by professional bodies. Two private hospitals in Britain have acted within this role by banning some advanced laparoscopic procedures until independent experts confirm that their surgeons are qualified to perform such techniques.[158]

Training of nurses and technicians is also important. The surgeon is reliant on the picture shown by the video equipment; poor-quality pictures make the operation longer and more difficult. Technicians have to know how to maintain and keep in top working order a greater range of such equipment, equipment that is evolving rapidly. Operating room nurses need the skills to assist at a range of laparoscopic procedures as well as their open surgical alternatives. Staff need to be confident in handling and cleaning a variety of complex items, such as endoscopes, cameras, insufflators, video monitors and laparoscopic instruments. Cleaning protocols for such equipment and instruments are different from those for open surgical instruments, and many items are more readily damaged.

Conversion to open operation

A low threshold for conversion to open procedures is important in any circumstance where an optimum operation is not feasible, such as where definition of anatomy is poor.[57] Some conversions will be inevitable, even with the most careful patient selection. Judgement by the surgeon is needed to determine when the laparoscopic approach must be abandoned in the interests of safety and optimal outcome. Higher conversion rates can be expected early in the introduction of a new laparoscopic procedure and early in an individual surgeon's experience. The high conversion rate (14.3%) of laparoscopic to open cholecystectomy in Australia in 1991–92 should be seen in that context.[33] The rate has dropped to 8.4% in 1992–93 as experience has been gained, and may drop further still. Rates in some States are already below this figure.[36]

Day surgery

The availability of laparoscopic surgery increases the likelihood of undertaking many procedures as day surgery. Procedures such as laparoscopic hernia repair, where open alternatives can already be performed as day cases, are obvious candidates. More complex procedures such as laparoscopic cholecystectomy have been suggested as suitable for day surgery in a proportion of cases.[159] Performance of laparoscopic procedures in day surgery centres should follow the same standards applied to other day surgery procedures. Important considerations are careful patient selection, adequate patient information, skilled surgeons and anesthetists, good post-operative analgesia and good overall management.

Post-discharge patient follow-up becomes increasingly important as hospital stays shorten with laparoscopic techniques, particularly in the day surgery setting. Since serious complications can follow any laparoscopic surgery, contact needs to be maintained with patients after discharge. Good organisation and communication between hospitals and community care are important.[160,161] Outcome studies of laparoscopic surgery in the day surgery or very short hospital stay setting are needed to ensure that patient outcomes are favourable and complication rates are low.

Institutional factors may affect any move to laparoscopic day surgery. Lack of a financial incentive, or even higher initial costs due to set-up of suitable facilities, may affect a hospital's use of this alternative. Inadequate community care facilities or staff may be another deterrent.

It should not be forgotten that procedures such as laparoscopic cholecystectomy are still major surgical operations, even if patients do recover quickly from them. In the Netherlands the policy is that patients should be considered for day surgery only when the complication rate is anticipated to be below 2% and the readmission rate below 1%, and careful examination and pre-operative screening is considered necessary.[162] Evaluation is still needed to determine which laparoscopic procedures might be suitable for day surgery.

Patient issues

Informed consent by patients to laparoscopic procedures is important. Patients should be aware of the attendant risks of laparoscopic surgery, and of the uncertainties surrounding recurrence rates, long-term outcomes, and safety and efficacy of more experimental procedures. A difficulty with the 'laparoscopic revolution' is that the public's awareness of new procedures (driven in part by the media) has led to demand for particular procedures before their safety and efficacy are established or appropriate training and standards are put in place.

One side effect of the change to laparoscopic surgery is that it has directed attention to expectations of recovery periods and hospital stays following open surgery, and use of post-operative analgesia. Patients have had similar post-operative courses following laparoscopic and open fundoplication when their expectations of recovery were similar.[106]

Ethical issues

As has already been noted, laparoscopic cholecystectomy diffused at a time when there was little information comparing it with open cholecystectomy. As early as February 1991 Neugebauer et al. argued that resistance by patients and surgeons placed ethical constraints on the conduct of randomised controlled trials of the two procedures, and that comprehensive surveillance and monitoring of laparoscopic cholecystectomy was the only realistic method of assessment.[163]

However, a survey conducted the following year found that only a minority of both surgeons and hospital ethics committees surveyed thought that a trial of laparoscopic cholecystectomy with alternatives was unethical.[164] Given the higher rate of bile duct injury that has emerged with this procedure, despite early claims of improved safety over the open alternative, it is difficult to see how arguments about comparative trials being unethical could be applied to other laparoscopic procedures.

Institutional issues

An oft-cited advantage of laparoscopic surgery is the reduced hospital bed usage and consequently savings. Such savings may not be apparent to the hospital administrator unless it is possible to close wards rather than replacing one type of case with another. Few cost savings to the hospital are gained by closing single beds, since staffing levels

will not change. In addition, hospitals may incur costs through restructuring, training requirements, equipment and instruments (especially disposables). A Quebec report concludes that a hospital that uses beds freed by use of laparoscopic cholecystectomy for cases of equivalent intensity will incur an increased load on its budget of approximately CDN$464 per case.[42]

Laparoscopic surgery has imposed several changes upon hospitals. Shorter hospital stays increases administrative requirements and costs. Many laparoscopic procedures take longer than open alternatives, especially early in their introduction, increasing the demand for operating theatres. Widening indications and consequential higher national caseloads, as has occurred with cholecystectomy, place more demands on a number of hospital facilities, including operating theatres, cleaning and administration.

Instrumentation and equipment

Costs

Approximate costs of some laparoscopic equipment and instruments are summarised in Table A3.1 (Appendix 3). Three-dimensional video cameras are likely to cost considerably more than two-dimensional cameras, due to factors such as the large electronic processing required.

A Belgian study suggests that a hospital needs to perform more than 140 laparoscopic cholecystectomies annually before it becomes cost-effective to invest in laparoscopic equipment.[59] This number falls to 70 annually if operating times fall from an average of 2 hours to 1.5 hours. However, Cuschieri has suggested that there are no hard data on this topic and that cost considerations will have to take into account newer developments which include semi-disposable and limited reusable instrumentation.[165]

Reusable instruments cost $800 to $1,500, depending upon the type of instrument. Replacement parts such as jaws of scissors cost approximately $300–400. In comparison, disposable instruments cost $100 to $440. Those instruments not available as reusables, staplers and linear cutters, are at the top of this range.

Developments

Instrumentation is seen as a factor in improving operations by allowing them to be faster and easier to perform and by minimising complications. Laparoscopic instruments with greater ranges of motion, more force feedback and tactile discrimination are being developed, as are laparoscopic 'sewing machines' to facilitate suturing.[166] Bifunctional forceps (scissors and bipolar diathermy) and hemostatic clips to aid management of uterine vessels have been suggested as improvements that would decrease operation times for LAH.[167] Gill et al. suggest that development of multiple-load gastrointestinal anastomotic staplers for vascular and bowel work, the availability of absorbable staples, biological adhesives, laser welding, fan retractors and multifunction steerable instruments should all combine to make laparoscopic procedures simpler and easier.[117] Continuing improvements in a range of laparoscopic instrumentation can be expected in the future.

Similarly, developments in equipment will also assist the surgeon. Refinements of the recent major advances of three-dimensional video systems and gasless laparoscopy can be expected. High-density monitors capable of displaying multiple images and thin flat screen monitors are all advances likely in the near future.[10] Miniaturisation of optics to make performance under local anesthesia practical has been suggested as being helpful in using diagnostic laparoscopy for trauma.[128] An automatic endoscopic system designed to optimise camera positioning is under development. Laparoscopic stapling devices have been refined for use with a variety of specific tissues. While these devices are effective, they can be difficult to use and harsh with tissues.[10]

Consequently, alternative methods of tissue repair are being sought, such as laser tissue fusion.

Future developments in equipment will affect overall costs. Some will be cheaper alternatives. For example, gasless laparoscopy avoids the operative costs of insufflation, such as the cost of the gas and pneumoperitoneal needle, although the cost of the device itself is comparable to that of an insufflator. However, most will increase costs. Developments such as three-dimensional video systems are likely to be more expensive than the technology they are replacing. Moreover, the rate of technological change is such that the life of equipment is quite short, adding to hospital costs.

As an example, three-chip cameras give better colour and resolution than single-chip cameras, although the cameras are larger and more complex. However, another upgrade in the form of three-dimensional video systems is just on the market. This rapid evolution of equipment leaves hospitals in a quandary. Any purchases now might quickly become obsolete, but new developments are likely to be more expensive and possibly not as stable technically in their first release. On the other hand, a surgeon who becomes used to a certain level of technology and the advantages of it is likely to find it difficult to move back to a lower level of technology if moving to another hospital which does not have the same upgraded equipment.

As equipment and instruments continue to evolve, hospitals will be continually faced with these issues of cost and timing of upgrades. New equipment will need to be compared with that already in use to determine the degree of advantage it offers and if this is worth the additional cost. When to upgrade becomes important if equipment is constantly evolving. Continual purchase of new equipment places a strain on hospital budgets and erodes cost advantages of laparoscopic techniques.

Reusable versus disposable instruments

Since the introduction of laparoscopic cholecystectomy there has been discussion about the use of disposable versus reusable instruments. Initially, reusable instruments were difficult to clean and few types were available. However, they have evolved, with a wide range of instruments that can be taken apart for cleaning or replacement of parts available. Disposable instruments have been expensive, adding several hundred dollars to the cost of some laparoscopic procedures.

The total cost of either disposable or reusable instruments is hard to determine. As well as the purchase price, the cost of disposable instruments includes some administrative overheads, and disposal of the instruments after use. The cost of reusable instruments includes the costs of cleaning equipment, materials and staff, sufficient sets to cope with down time for cleaning and repairs, complications resulting from inadequate cleaning, repairs, training cleaning staff and slightly longer operations.

A company-funded study of the relative costs of disposable and reusable instructions in American hospitals found that repair, replacement and cleaning costs of reusable instruments were significant and concluded that disposable instruments could be used instead of reusables without impacting on costs.[168] However, administrative costs in processing disposable instruments do not appear to have been included in this analysis. Repairs, back-up instruments and processing equipment can add 44% to the purchase price of basic instrument sets.[124] A mix of reusable and disposable instruments has been suggested as economically advantageous when all aspects of instrumentation, turnaround time, staffing, processing, care and maintenance are considered.[169] Full economic evaluation of the advantages and disadvantages of disposable and reusable instruments is difficult, not only because of the factors already listed, but also because of the rapid evolution of this instrumentation plus alternatives such as limited reusable and semi-disposable instruments.

As well as cost, other issues arise in the debate on the relative merits of disposable and reusable instruments. Reusable instruments can be damaged or incorrectly assembled. However, the same applies to other equipment used for laparoscopic surgery, such as the endoscope itself.

Reuse of items marked as single use has often occurred, even though they are not designed to be cleaned and consequently sterilisation between patients may be difficult to achieve. Infection due to inadequate cleaning will always remain a potential problem of this type of surgery because equipment such as the endoscopes will still need to be sterilised between cases. With equipment and reusable instruments not only is the purchase price important. A good back-up service for parts and repairs and knowledgeable technical support are also needed.

Costs and funding

Some factors are very difficult to include in cost analysis and have been ignored in the costings presented in this report. One example is the cost of complications. If the rate of minor complications decreases but the rate of major complications increase following the change from open to laparoscopic techniques, the laparoscopic procedure will be more costly than it first appears. Changes in long-term recurrence rates also impact on costs.

Consequential morbidity is also important. In assessing the cost-effectiveness of medical therapy versus laparoscopic vagotomy for ulcers, avoiding the potential risk of a perforated ulcer and side effects of the drugs should be weighed up against long-term sequelae of surgery such as dumping syndrome or diarrhoea. A consideration in respect to widening indications for cholecystectomy is the increased number of people who are without their gall bladder, and any later morbidity that might entail.

Even more difficult to assess are intangibles such as the value patients place on a faster recovery or a better cosmetic result.

Some issues relating to funding have already been discussed. One other issue relates to the use of funding mechanisms to progress changes in clinical practice. Where a laparoscopic procedure is proven safe and cost-effective relative to alternatives, funding mechanisms can be a useful method of assisting diffusion of the procedure into routine clinical practice. However, in a number of instances, including high-volume procedures such as hernia repair and hysterectomy, the laparoscopic alternative has either not been standardised from a clinical perspective, or has not been proven safe and effective relative to traditional approaches. Until a laparoscopic procedure has in fact been clearly shown to be safe and cost-effective, and appropriate indications determined, use of funding mechanisms to speed its adoption would seem to be premature and carry the risk of forcing an inappropriate change to routine health care. In such a case both patients and health care budgets are likely to suffer.

Conclusions

When laparoscopic cholecystectomy was first introduced, minimal access surgery was predicted to make a major impact on health care in the 1990s, both in the way surgery is practised and on costs.[160,170,171] It was suggested that most abdominal surgery would be performed laparoscopically within ten years, with considerable benefits to the costs of surgery and patient recovery. In Canada, 75% adoption for laparoscopic cholecystectomy was reached in 10 months for large hospitals and 29 months for small hospitals.[37] Diffusion appears to have been as rapid in Australia, to the point that 74% of cholecystectomies are now performed laparoscopically. However, it is becoming clear that not all the predicted benefits and effects of laparoscopic surgery will necessarily occur. Certainly diffusion of other major laparoscopic procedures has been slower, reflecting less clear-cut advantages of these procedures over alternatives.

Laparoscopic cholecystectomy diffused with minimal regulatory delay and without prior proof of effectiveness or assurance of appropriate training for surgeons and other hospital staff. However, subsequently a higher-than-expected rate of bile duct injury has emerged and is of concern. Cost advantages to the Australian health care system have not yet been fully realised due to a higher overall cholecystectomy rate following the introduction of the laparoscopic method.[33] Whether this higher caseload is permanent (due to widening indications) is not clear, though it is of interest that similar increases in rates for cholecystectomy have been reported from the USA.[27,31,34,35] It is possible that similar increases in rates for other procedures might occur, where the laparoscopic approach replaces most open operations.

With a number of laparoscopic procedures, their advantages over open alternatives in terms of shortening hospital stays and recovery times and reducing costs is not as clear-cut as was the case with cholecystectomy. As a result, diffusion has been slower and final laparoscopic caseloads are difficult to determine until more information about procedures is available.

Questions about safety, efficacy and long-term results remain with many procedures. Even with laparoscopic cholecystectomy, concerns about a higher rate of bile duct injury have arisen. One danger is that the expectations of patients for a minimally invasive procedure with rapid subsequent recovery will encourage faster diffusion than is warranted given the questions still to be answered.

Laparoscopic procedures fall into three categories: those in routine clinical use, those known to be safe and efficacious but whose cost-effectiveness is not established, and those that are still experimental. Both the last two groups need further evaluation. For experimental procedures, studies establishing their safety and efficacy are required. For the second group, on the other hand, studies to establish the comparative cost-effectiveness of the procedure in question with its open surgical alternative are needed instead. One view is that even those in routine clinical use should also be validated through appropriate trials.

Other high-volume procedures for which laparoscopic approaches have been introduced are appendicectomy, hernia repair and hysterectomy. The impact of LAH is likely to be in replacing abdominal rather than vaginal hysterectomies; LAH basically allows an abdominal hysterectomy to be done vaginally, with consequential reductions in post-operative pain, lengths of hospital stays and recovery periods. Hysterectomies performed for menorrhagia are being replaced by hysteroscopic endometrial ablation; the impact of LAH will be on abdominal hysterectomies performed for other indications.

Because hospital stays were already short following appendicectomy and hernia repair, it is not clear if the laparoscopic approach offers significant advantages over more traditional approaches. Further information about both procedures is needed before the impact of the laparoscopic approach can be determined. Concerns have also

been raised about the safety of laparoscopic hernia repair, and suggestions made that its use should be restricted to controlled clinical trails.

Some laparoscopic procedures may prove to be less safe, efficacious or cost-effective than alternatives and not diffuse into routine clinical use. Others may become one of a range of alternatives available to the clinician. For example, laparoscopic bladder suspension may be added to the array of therapies for incontinence. Technically difficult laparoscopic procedures such as colon resection may be performed only by a small number of specialist centres. In some instances there may be a shift from other types of treatment. For example, it is possible that laparoscopic vagotomy and fundoplication may replace some medical therapy for ulcers and gastroesophageal reflux.

While it is not possible at this stage to predict the final mix of laparoscopic and open procedures, it is evident that laparoscopic surgery will continue to replace much open surgery and to have an impact on hospital infrastructure and resources.

A number of issues concerning laparoscopic surgery are listed in Table 18. Some of these were discussed in the earlier report[6] and still need addressing, others are now less of a problem and some have emerged recently. One of the more important in terms of its cost implications is the rapidly evolving nature of both equipment and instrumentation. Much equipment has a relatively short lifetime. Another is the question of judging when the level of increase in major complication rates is no longer acceptable. A third is public demand, and funding mechanisms, driving diffusion of a laparoscopic procedure before it is proven safe and cost-effective

In terms of direct costs to treat individual patients, some laparoscopic procedures, such as cholecystectomy and vagotomy, offer advantages over open alternatives. For others, such as appendicectomy, hernia repair and hysterectomy, cost advantages are not as clear-cut and may not exist; in fact, the laparoscopic approach could turn out to be more expensive. Differences in direct procedure costs depend on a number of factors, including the mix of disposable and reusable instruments used and the length of hospital stay of laparoscopic procedures in routine clinical practice. Other factors affecting costs are complication and recurrence rates.

Overall cost advantages to the health care system are influenced by changes in indications and in the number of open procedures replaced by laparoscopic alternatives. If indications widen, costs to the health care system may not decrease even though laparoscopic alternatives are cheaper, although patients may be better off.

One of the major benefits of laparoscopic surgery is the faster return to work or other activities. This benefit is apparent even when direct cost advantages are doubtful. It has implications in terms of increased productivity in the workplace and reduced need for formal and informal care at home.

Thorough assessment of laparoscopic procedures is needed to determine which are safe, efficacious and cost-effective. Uncertainties about long-term complication and recurrence rates, appropriate indications and results in routine clinical use need to be resolved if patients, the community and the health care system are all to benefit from the 'laparoscopic revolution'.

Minimal access surgery will continue to pose challenges for clinician and administrator alike. Initiatives undertaken to address these will continue to be relevant for some time to come. Laparoscopic surgery is an area of health care technology of great promise, with benefits to patients and the potential to produce savings for the health care system. However, it is important that individual procedures be validated in terms of their safety and effectiveness, that training be adequate and laparoscopic procedures used appropriately, and that issues relating to infrastructure be addressed.

Table 18: *Issues in laparoscopic surgery*

Training and safety
Adequate training of surgeons
Ongoing audit of procedures
Availability of adequately trained theatre staff
Availability of adequately trained technicians
Changes to usual surgical practice
Reluctance to convert a laparoscopic procedure to an open one
Development of appropriate indications for each operation
Safety needs to be proven before widespread use
Inadequate information available on success rates, morbidity, cost-effectiveness and long-term effects
Inadequate information available comparing each new laparoscopic procedure with its alternatives
Long-term recurrence rates (for example, for hernias) not known
Possible spread of neoplastic cells
Outpatient surgery and its safety and application
Possible inappropriate widening of indications
Post-discharge follow-up
Informed consent for new procedures
Public demand before procedure proved safe
Minimum annual caseload for different laparoscopic procedures
Equipment and instrumentation
Cost-effectiveness of reusable versus disposable instruments
Adequate cleaning of equipment
Cost of environmentally friendly way of disposing of single-use instruments
Compatibility of instruments from different suppliers
Compatibility of video equipment within a hospital
Costs
Increased instrumentation and equipment costs
Increased theatre costs (longer times and set-up for open procedures)
Rapid changes in technology impacting on costs
Faster turnover of patients
Long-term changes in types of hospital facilities needed
Cleaning of reusable instruments
Changes in exchange rates affecting costs
Increased cholecystectomy caseload
Cost structure providing disincentive for hospitals to change
Funding mechanisms driving acceptance before procedure proven safe and cost-effective

Appendix 1: Terminology and definitions

Terminology and definitions

Two terms have been used in connection with the new surgery: minimally invasive therapy (MIT) and minimal access surgery (MAS). MIT refers to all those less-invasive or non-invasive procedures that have replaced open operations. MIT includes non-invasive techniques such as extracorporeal shock wave lithotripsy (ESWL), focused ultrasound, percutaneous procedures and endoscopic procedures such as laparoscopy and arthroscopy. MAS refers to surgery which reduces the trauma of access while allowing adequate exposure of the operating field. As such, MAS encompasses the laparoscopic, endoluminal, perivisceral endoscopic (dissection around a viscus), thoracoscopic and arthroscopic approaches. These approaches take place at the end of some sort of endoscope. Access to the operating field is gained either through one of the body's natural orifices or through tiny (popularly known as 'keyhole') incisions.

Laparoscopy was used regularly in the 1980s in gynecology for diagnosis and surgical procedures such as tubal sterilisation, treatment of endometriosis and aspiration of ovarian cysts. A number of other gynecological procedures, such as myomectomy and the treatment of ectopic pregnancies, had been performed laparoscopically but were not in routine clinical use. Laparoscopy was also in use for diagnosis of liver disease and peritoneal problems.

In 1987 a laparoscopic approach to cholecystectomy was first described. Since then it has diffused rapidly and is now regarded by many as the treatment of choice for gallstone disease.[3,4] Laparoscopic approaches to many other operations in the abdominal and pelvic cavities have been developed and some, such as laparoscopic appendicectomy, are also spreading.

Thoracoscopy is not a new technique, but developments in laparoscopy are spreading to this field. Previous routine uses include diagnosis and division of pleural adhesions, with recent developments including wedge resection of the lung and sympathectomy.

Arthroscopy was also developed many years ago and has been in routine clinical use in the knee for diagnosis and for surgical procedures such as meniscectomy, synovectomy and meniscal repair. Its use has extended to other joints, including the wrist, elbow, shoulder, ankle and temporomandibular joint.

Endoluminal surgery (surgery using an endoscope inserted into one of the body's orifices) is less invasive than the approaches already discussed, since no incision is needed to gain access to the operating field. Less extensive surgery is generally performed, since instruments are normally inserted through an operating channel in the endoscope rather than through one or more separate ports. Examples of such surgery include hysteroscopic endometrial ablation, transurethral laser lithotripsy, endoscopic ligation of esophageal varices and removal of tracheobronchial obstruction.

Glossary

ablation	extirpate (utterly destroy) tissue
adrenalectomy	surgical excision of one or both adrenal glands
antrectomy (pyloric)	surgical excision of the pyloric antrum (or chamber) of the stomach
atelectasis	incomplete expansion of all or part of a lung, collapse or airlessness of a lung
blebectomy	surgical excision of a bleb, or localised collection of fluid
cholangiography	radiography of the bile ducts
cholecystectomy	surgical removal of the gall bladder
cholelithiasis	presence or formation of gallstones
colostomy	surgical creation of an opening between the colon and the surface of the body
direct inguinal hernia	a hernia in which the sac does not leave the abdominal cavity through the abdominal inguinal ring but through a defect in the floor of the inguinal triangle
dysphagia	difficulty in swallowing
embolisation	therapeutic introduction of a substance into a vessel in order to occlude it
femoral hernia	hernia into the femoral canal
fundoplication	folding the fundus of the stomach around the esophagus, usually for treatment of gastroesophageal reflux
gastrectomy (subtotal)	excision of part of the stomach
gastroenterostomy	surgical creation of an artificial passage between the stomach and small intestine
gastropexy	surgical fixation of the stomach to correct displacement
hernia	abnormal protrusion of a loop or knuckle of an organ or tissue through an opening
hernioplasty	plastic operation for the radical cure of hernia
herniorrhaphy	any operation which includes suturing for the repair of a hernia
hiatus hernia	protrusion of any structure through the esophageal hiatus of the diaphragm
hyperhidrosis	excessive sweating, with the sweat often accumulating in visible drops on the skin
hysterectomy	excision of the uterus
indirect inguinal hernia	a hernia that follows the spermatic cord into the scrotum or, in the female, the round ligament into the labium majus
inguinal hernia	hernia into the inguinal canal; there are two types — direct and indirect
LAH	laparoscopically assisted hysterectomy
leiomyoma	benign tumour derived from smooth muscle
lymphadenectomy	surgical excision of one or more lymph nodes
MAS	minimal access surgery
menorrhagia	excessive bleeding at the regular intervals of menstruation

MIT	minimally invasive therapy, or all those less-invasive or non-invasive procedures that have replaced open operations; includes MAS
nephrectomy	surgical excision of a kidney
nephroureterectomy	surgical excision of a kidney and all or part of the ureter
pericardiectomy	excision of part of the pericardium (or membranous sac enveloping the heart)
perineal	pertaining to the perineum, i.e. the pelvic floor and associated structures
pleural effusion	the presence of liquid in the pleural space
pneumoperitoneum	presence of gas or air in the peritoneal cavity
pneumothorax	accumulation of gas in the pleural space
polypectomy	surgical removal of a polyp
prostatectomy	surgical removal of the prostate or part of it
pyloroplasty	enlargement of the opening from the stomach to the duodenum to relieve pyloric obstruction or accelerate gastric emptying
resection	excision of a portion of an organ or other structure
retropubic	behind the pubic bone
sympathectomy	excision of a portion of the autonomic or sympathetic nervous system
trocar	central obturator of a sharp-pointed cannula (or tube); once both obturator and cannula are inserted the cannula is removed
ureterolithotomy	removal of a stone from the ureter by incision
ureterolysis	the operation of freeing the ureter from adhesions
vagotomy	surgical division of branches of the vagus nerve, usually for treatment of peptic ulcer
varicocele	a varicose condition (i.e. dilatation) of the veins in the scrotum
varicocelectomy	surgical excision of dilated spermatic veins for relief of varicocele

Appendix 2: Hospital morbidity data

Hospital morbidity data are collected by State health authorities on the basis of discharges from hospitals. Data for public and private hospitals in New South Wales and South Australia, and public hospitals in Victoria have been used in preparing this report.

These data were coded using the ICD-9-CM coding system. The procedure codes used were:

repair of inguinal hernia — 53.0, 53.1

repair of femoral hernia — 53.2, 53.3

repair of incisional and other anterior wall hernia — 53.5, 53.6

repair of diaphragmatic hernia — 53.7, 53.8

repair of umbilical hernia — 53.4

repair of other hernia — 53.9

appendicectomy — 47.0, 47.1

cholecystectomy (open) — 51.22

liver biopsy — 50.11, 50.12

vagotomy — 44.0

fundoplication and other procedures (than esophagogastroplasty) for creation of esophagogastric sphincteric competence — 44.66

hemicolectomy, total colectomy and other large intestinal excision or anastomosis — 45.7, 45.8, 45.9

orchidectomy — 62.3, 62.4

laparotomy for division of adhesions — 54.5

laparotomy for exploration, control or bleeding or drainage of abscess — 54.1

hysterectomy — 68.3, 68.4, 68.5, 68.6, 68.7

Appendix 3: Cost estimates

Financial costs to service providers (i.e. hospitals and government health services) for each procedure have been estimated on a per patient episode basis. Costs include the hospital component of the procedure but exclude pre-operative and post-discharge consultations, since these are similar in all cases. Costs were estimated as follows:

- hospital costs were estimated on a per day basis for all public hospitals, adjusted to exclude fees for visiting medical officers;
- hospital costs were calculated from the cost per bed-day (obtained for the Hospital Utilisation and Costs Study) and the average length of stay;
- medical fees were added separately and were taken from the Medicare Benefits Schedule, using the 75% rebate of the Schedule fee since this is the cost to government and all procedures would normally be performed in a hospital or day care facility;
- hospital and medical costs do not include the cost of training surgeons and theatre staff in the new procedures;
- capital costs for larger items of equipment and costs of disposable instruments were added separately;
- since retreatment rates and rates of conversion of endoscopic procedures to open procedures can be significant, the cost of these were included to derive a cost per patient rather than a cost per procedure;
- the cost of complications is likely to be different for the different procedures, but has not been included due to insufficient information being available to allow these costs to be estimated accurately.

Prices for equipment and instruments are as at December 1993, and were derived from information supplied by the following organisations:

Auto Suture, Australia
Endovision Pty Ltd
Johnson & Johnson Medical Pty Ltd
N Stenning and Co
Selby Scientific and Medical Pty Ltd
William A Cook Australia Pty Ltd
Bard Australia Pty Ltd
Smith and Nephew Richards
C-V & Endoscopy Services
Getz Bros & Co Pty Ltd

Table A3.1: *Cost of selected equipment and instruments for laparoscopic surgery*

Description	Purchase price ($A)
Equipment	
Video camera (two-dimensional)	17,000 – 27,000
Video monitor	2,000 – 4,000
Insufflator	10,000 – 17,000
Light source	8,000 – 12,000
Laparoscope	4,000 – 5,000
Device for gasless laparoscopy	12,000
Reusable instruments	600 – 1,550
Disposable instruments	100 – 440
Cholecystectomy set	540 – 560
Hernia repair set	410 – 570

Table A3.2: *Cost of open surgery* [a]

	Cost per patient episode ($)			
Item	Appendic–ectomy	Hernia repair	Vagotomy	Fundoplication
Surgeon's fee [b]	238	248	477	465
Assistant's fee [b]	46	46	95	93
Anesthetist's fee [b]	78	78	148	176
Hospital costs [c,d]	1,847	1,508	5,730	4,976
Total	**2,210**	**2,069**	**6,450**	**5,714**

(a) Only the hospital procedure was costed. Pre-operative and post-discharge consultations are common to all procedures and have been excluded.

(b) Estimated as 75% of fees from the Medicare Benefits Schedule.[172] Item numbers used were 30500, 30527, 30571, 30614, 51300 and 51303.

(c) Hospital costs were calculated from the cost per bed-day and the average length of stay. A cost per bed-day of $377 was used, derived from average bed-day costs for public hospitals from the Hospital Utilisation and Costs Study and brought to 1991–92 prices using health expenditure deflators.[173,174] This cost excludes fees for visiting medical officers but includes salaries and wages for other medical staff as well as for non-medical staff. It also includes non-salary recurrent expenditure such as surgical and drug supplies. This makes the assumption that surgical and drug supplies used in each procedure is constant (which may not be the case). Larger capital items are excluded.

(d) Average lengths of stay obtained from State health authority hospital morbidity data, and were 4.9 days for appendicectomy, 4.0 days for hernia repair, 15.2 days for vagotomy and 13.2 days for fundoplication.

Table A3.3: *Cost of laparoscopic procedures* [a]

Item	Cost per patient episode ($)			
	Appendic-ectomy	Hernia repair	Vagotomy	Fundoplication
Surgeon's fee [b]	256	246	477	465
Assistant's fee [b]	46	46	95	93
Anesthetist's fee [b]	78	78	148	176
Equipment costs [c]	84	84	84	84
Instrument costs [d]	0	270	380	380
Hospital costs [e,f]	1,131	1,131	1,885	1,885
Conversion to laparotomy [g]	148	56	799	709
Total	**1,743**	**1,912**	**3,868**	**3,795**

(a) See footnote 1, Table A3.2.

(b) Estimated as 75% of fees from the Medicare Benefits Schedule.[172] Item numbers used were 30572, 30609, 51300 and 51303. Laparoscopic vagotomy and fundoplication have not been included in the Schedule at this stage, so as an estimate the rebate for the open approaches (item numbers 30500 and 30527) were used.

(c) Equipment was assumed to be dedicated and was annuitised with a 5% discount rate on a three-year basis with a patient throughput of 300 per year. Average costs for each type of equipment were used.

(d) Costs of disposable laparoscopic staplers and linear cutters. Assumes all other instruments used are reusable and that their costs are included in the hospital costs items.

(e) See footnote c, Table A3.2.

(f) Average lengths of stay of 3 days were used for laparoscopic appendicectomy and hernia repair, based on the studies summarised in Tables 10 and 12. Average lengths of stay of 5 days were used for laparoscopic vagotomy and fundoplication, based on a limited number of case reports and small studies available.

(g) Conversion rates of 3.0% and 6.7% were used for laparoscopic appendicectomy and hernia repair respectively, based the studies summarised in Tables 10 and 12. A conversion rate of 12.4% was used for laparoscopic fundoplication.[106] No information was available for conversion rates of laparoscopic vagotomy, and the laparoscopic fundoplication rate was used.

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