

MINIMAL ACCESS SURGERY

- *Reasons for current rapid growth*
- *Training and other issues*
- *Resource implications for the NHS*

Minimal Access (or 'keyhole') **Surgery (MAS)** has spread rapidly in the last 5 years and is now the dominant method for some operations (e.g. gall bladder removal). These techniques reduce post-operative pain and complications, give faster recovery times, as well as the obvious cosmetic benefits. Nevertheless, there are concerns over the potential safety, cost and logistical implications of the rapid and largely uncontrolled adoption of some MAS procedures in the UK.

In view of the parliamentary interest in MAS, the POST Board decided to conduct a study. This note summarises the findings of the full report¹.

BACKGROUND

The miniaturisation of video cameras and surgical tools have revolutionised diagnostic and surgical procedures alike, and opened up a whole new field of minimal access techniques (see **Box 1** for some technical details). Now, many operations across a wide range of surgical specialties can be performed using MAS approaches. Advantages are clear in reduced pain, scarring, hospital stays etc., and MAS has become popular with patients, health service administrators, and with surgeons who see considerable professional, intellectual and research opportunities arising from minimal access methods. This potent mixture of demand 'pull' and technological 'push' means that surgeons have embraced the new techniques enthusiastically.

However, no type of surgery is entirely risk-free, and a number of well-publicised cases where patients have suffered have highlighted concerns over the adequacy of surgeons' training in the new techniques. Moreover, formal evaluation of the cost-effectiveness and safety of MAS (e.g. compared to conventional surgery) has been largely overlooked in the rush to use minimal access methods, with the result that many of the potential benefits have yet to be proven by medical audit or clinical trials. Such concerns have sparked much recent activity by organisations such as the NHS, Department of Health (DH), Medical Research Council (MRC) and the professional bodies (e.g. Royal Colleges) to regulate the use of MAS more carefully until the potential risks and benefits have been formally evaluated. These measures are described in the full report and their policy implications assessed.

1. The full report "Minimal Access ('Keyhole') Surgery and its Implications" is available (free to Parliamentarians, £12 otherwise) from POST (0171-219-2840).



POST
REPORT
SUMMARY

68

October
1995

*This is a summary of a 38-page report
available from the PARLIAMENTARY
OFFICE OF SCIENCE AND TECHNOLOGY
(extension 2840).*

Box 1 WHAT IS MINIMAL ACCESS SURGERY?

Conventional surgical procedures consist of three main stages: cutting the patient open; removing or repairing an organ or tissue; and closing the patient up again. In minimal access surgery, the impact of the first and last of these is reduced as far as possible, either by gaining access to the body through natural orifices or by operating through very small holes (typically 5-15 mm across) cut into the body. The development of fiberoptic light sources, miniature video cameras and specially designed (e.g. cutting, grasping, stapling) tools has allowed increasingly complex surgery to be performed, with the surgeon being guided by high resolution, magnified video images. Other terms for MAS include minimally invasive surgery, keyhole surgery and endoscopy.

Equipment needs vary from one type of operation to another. Most applications require a basic package comprising imaging, surgical and other medical equipment, as well as access to back-up facilities. The vast majority of minimal access techniques rely on video images, although other systems using ultrasound, magnetic resonance, etc. have been developed. The most recent video imaging systems - based on miniaturised 'three chip' cameras and fiberoptic light sources - provide high quality, magnified colour images. They are displayed on two or more high resolution TV monitors to ensure that all members of the operating team (surgeon, anaesthetist, 'scrub' nurse, etc.) can also observe.

Access to the body may be achieved via a range of different sized 'ports' and organs or tissues can be cut, held, dissected, burned, stapled, retrieved, etc. via specialised tools and attachments which the surgeon operates through the various ports.

CURRENT AND POTENTIAL USAGE OF MAS

MAS techniques were originally developed to assist diagnosis, and are still widely used for this purpose. They were first applied to surgical procedures in specialties such as gynaecology, urology and orthopaedics, and are now the standard method of choice for many such operations. More recently, a whole new range of MAS procedures have been developed with the advent of **laparoscopic** techniques - operations carried out through ports in the abdominal wall - and it is the diffusion of these techniques into clinical practice in recent years that has focused attention on the safety, effectiveness, etc. of minimal access surgery.

The extent to which MAS approaches have entered surgical practice can be judged from figures in the full report. In the field of urology, endoscopic surgery accounts for around 84% of bladder operations, 81% of those on the outlet of the bladder and prostate, 71% involving the ureter, 44% of those on the urethra and around 8% of those involving the kidney. MAS is also

well established in orthopaedic surgery (e.g. over 17,000 endoscopic operations were conducted on the cavity of the knee joint in 1993/94) and in gynaecology, where it accounts for just over 60% of all therapeutic operations (mainly female sterilizations) on the fallopian tubes.

With the newer laparoscopic procedures, information is less readily available, because the coding system is running behind developments in surgery. The full report suggests that some statistics considerably underestimate the extent of MAS - e.g. with cholecystectomy (gall bladder removal), laparoscopic procedures may have risen from 10-20% in 1990 to between 70% and 85% of such operations now.

The full report also looks at the extent to which MAS could replace conventional surgery. One often-cited prediction suggests that 10 years from now some 70% of operations will be conducted endoscopically, but this is now widely viewed as an overestimate, and the 'market penetration' of MAS may be restrained by recent developments in training, evaluation and regulation. Nevertheless, the health-care industry is working on the assumption that up to 50 procedures in some 7 surgical specialties could be performed routinely by MAS by the year 2000, accounting for around 40% of all operations conducted in the UK.

PROS AND CONS OF MAS

A summary of the potential positive and negative impacts of MAS is given in **Table 1**. Most of the potential advantages stem from the reduced trauma relative to conventional surgery and reduced hospital stays (**Figure 1**). There are, however, potential disadvantages which have their roots in the increased complexity of many MAS approaches, surgeons' lack of familiarity with them, and uncertainty over their long-term implications. The full report examines these.

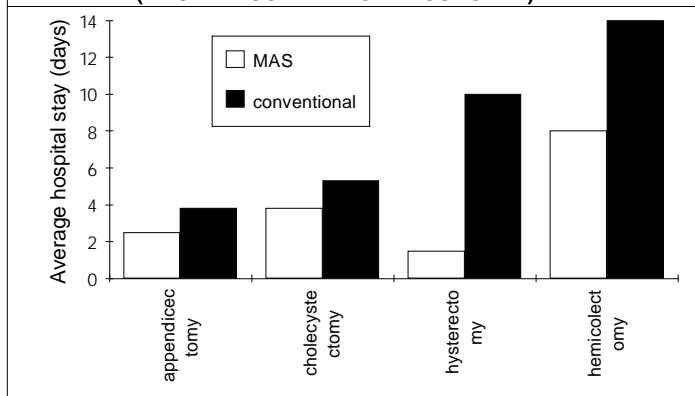
The main concern is over the danger - particularly in inexperienced hands - of accidental injury. Some studies have shown high rates of bile duct injury during gall bladder removal (up to 7%) in centres where surgeons lack experience of laparoscopic techniques. Injury rates decrease with practice, and the overall rate of bile duct injury for laparoscopic cholecystectomy is 0.33% - still significantly higher than the corresponding rate associated with open surgery (0.06%).

Injury rates for other laparoscopic operations are around 3.6% for appendicectomy, 10% for hernia repair, and 6% for colon and rectal surgery. These may however reflect a lack of familiarity with the new procedures, and may thus decrease significantly as surgeons gain experience of laparoscopic operations. However, a worry is that some complications reported are of a severity and type not seen with conventional approaches, such as major vascular injury during laparoscopic hernia repair.

Table 1 SUMMARY OF POTENTIAL PROS AND CONS OF MAS

<i>Potential Advantages</i>	<i>Potential Disadvantages</i>
Reduced post-operative pain	Increased short-term complications (e.g. due to errors)
Shorter hospital stays	Increased long-term complications (e.g. due to changes in surgery)
Accelerated recovery	Increased mortality
Shorter periods of disability	
Improved opportunities for audit	
Cosmetic benefits	
Reduced short-term complications (e.g. wound infections)	
Reduced long-term complications (e.g. adhesions)	
Reduced mortality	

FIGURE 1 HOSPITAL STAYS FOR OPERATIONS (MAS AND CONVENTIONAL SURGERY)



COST-EFFECTIVENESS

Economic penalties and benefits associated with the use of MAS are shown in **Table 2**. On the plus side, MAS may reduce costs through shorter hospital stays and periods of convalescence, and by reducing complication rates and analgesic requirements, while factors such as patients being able to make an earlier return to work may have wider economic benefits. But on the minus side, longer operating times (at least until surgeons become familiar with an operation), high capital and running costs, and the possibility of an increase in both medical complications and demand for operations may all act to increase costs.

The full report examines the cost-effectiveness of MAS in more detail, and finds that while laparoscopic cholecystectomy is more cost-effective than the corresponding conventional operation, this may not be typical of other MAS operations. A certain throughput of patients is required in order to justify the initial outlay on the expensive MAS equipment - for basic MAS operations, the break-even point has been estimated at 140 patients per year using low cost (i.e. non-laser, sterilisable) equipment, rising to around 300 if more expensive laser equipment is used. A recent review concluded that only with cholecystectomy was there sufficient evidence of benefits to patients to justify more widespread adoption. Greater caution was advocated in other cases (see full report for details).

ISSUES

Evaluating New Techniques

The full report describes concerns that MAS techniques

Table 2 FACTORS AFFECTING COSTS OF MAS

<i>Factors decreasing costs</i>	<i>Factors increasing costs</i>
Reduced hospital stays	Longer operation times
Shorter convalescence	High 'running' costs
Reduced analgesic requirement	High capital costs
Reduced complications	Increased complications
Early return to work	Increased demand
Increased patient throughput	

are spreading without the benefit of assessments as to whether they are better than the techniques they replace on both medical and cost grounds. The report thus examines what techniques might be used for evaluation, and what are the main priorities.

In the latter context, there is considerable discussion underway in various bodies including the NHS Research and Development Directorate (RDD)'s Standing Group on Health Technology (SGHT), the DH's Policy Research Programme (DHPRP) and the MRC. Laparoscopic cholecystectomy is of particular interest because of the rapid rate of uptake. As a first step, the Royal College of Surgeons is preparing a review of the current state of knowledge (expected by end 1995). DHPRP is also commissioning other reviews on the role of MAS in treating cancer of the gastrointestinal tract, prostatic disease, appendicitis and cancer of the lung. In addition, DHPRP has recently funded a comprehensive review of Medical Laser Technology, and is currently supporting a trial comparing a new MAS treatment (trans-cervical endometrial ablation) for abnormal menstruation against standard hysterectomy.

Overall, clinicians agree on the need for further evaluation of new MAS procedures, and over the main priorities identified. Differences emerge however over the best way to proceed. For instance there is a debate over the most appropriate evaluation methods (discussed in the full report), and some concern that the whole evaluation process is proceeding too slowly. Thus, of the various priorities outlined above, only four are currently the subject of (MRC-funded) trials - hysteroscopic endometrial resection, hernia repair (2 trials), and treatment of colorectal and gastric cancer. This is a potential concern, since the 'window of opportunity' for trials to be conducted is limited by the tendency for new surgical techniques to spread rapidly into clinical practice anyway. **There is thus a danger that unless further evaluative trials are given a higher priority, the opportunity will be lost and the techniques will become widely used despite the lack of formal assessment.**

This position has already been reached with laparoscopic cholecystectomy, which is now so widely used in the UK as to render formal evaluation extremely difficult. Indeed, some surgeons consider that the benefits of the laparoscopic procedure are already well established, and suggest that the potential disadvantages all stem from surgeons' lack of familiarity with the technique.

On this analysis, little would be gained from carrying out evaluations and resources could be better utilised in training and audit. For other procedures not so well established however, one option would be to 'buy' the time needed for proper evaluation by regulating more carefully the way in which new surgical techniques are introduced.

Controlling the Rate of Introduction

Cases where patients have been injured - or even died - following supposedly routine 'keyhole' surgery have focused attention on how to control the introduction of such procedures in the future. A possible scheme has been proposed by the Senate of the Royal Surgical Colleges of Great Britain and Ireland.

This proposal operates in stages - once a new development has been 'detected', its use will be restricted initially to specified centres, where it will be evaluated in clinical trials. Once the value (in terms of safety, effectiveness, cost-effectiveness, etc.) of the new technique has been established to the satisfaction of the professional bodies and the DH RDD, its use will be restricted to those surgeons who have received the appropriate training. Eventually, if the procedure becomes sufficiently widely used, it will be included as part of the basic surgical skills assessment. Finally, the performance of the new procedure and of the surgeons using it will be monitored by a process of on-going clinical audit.

One issue which arises is whether legislation is required to introduce such a system. The full report describes disagreement over this question between bodies such as the Advisory Council on Science and Technology (ACOST) which argued for a registration scheme for novel surgical procedures and surgical teams, and professional bodies such as the Royal Colleges which see little to be gained from legislation. The DH sees regulation in this area as a matter for professional judgement and guidance rather than legislation, and is talking to the Royal Colleges about a new system that will bring together groups of experts under the auspices of the Royal Colleges to evaluate major advances in surgery and medicine.

Training, Certification, Continued Education

Minimal access surgery requires totally different skills than conventional surgery. For instance, surgeons need to learn different hand-eye coordination ('psychomotor') skills in order to manipulate the imaging and surgical equipment; tissue appears significantly different when viewed from inside the body; care must be taken to avoid accidental damage, particularly when using certain types of laser, or the somewhat crude 'grasping' instruments that have replaced the surgeon's hands.

The rapid growth of MAS in the early 1990s focused attention on the lack of formal training requirements for MAS, and precipitated a number of initiatives.

Considerable resources have now been mobilised to address the perceived shortcomings; including:

- Government and charitable support has allowed four **special minimal access training centres** to be set up in London (MATTU), Leeds (LIMIT), Dundee (MATTUS) and Cardiff.
- The Senate of the Royal Surgical Colleges published new training requirements covering, *inter alia*, MAS. **Basic Surgical Training** is designed to give trainees the basic skills used in all surgical specialties, such as suturing, dissection, etc. The next step is to undergo **Higher Specialist Training** to furnish the surgeon with experience and skills needed to perform operations in their area of specialty. Finally, surgeons will be required to participate in **Continuing Medical Education (CME)** to make sure that they retain competency in their existing specialties and catch up with new ones.

The full report discusses how these schemes will work in practice and issues of:

- timescales (how long will it take for the various training courses to become available?);
- selection of trainees;
- the role of the training centres;
- safety considerations;
- how to encourage the spread of certification and CME among existing surgeons;
- issues concerned with certification.

Auditing and Improving Clinical Practice

The report reviews the role of clinical audit in raising the overall quality of clinical care relevant to MAS. This raises a number of issues, including what should be done where individuals fall below the required standards (in spite of continuing medical education), how better clinical practice can be encouraged to spread throughout the profession, and how to improve the quality of information collected on surgical procedures, on which audit programmes depend, including better clinical outcome indicators.

A key question is **whether or not audit data should be published** to allow patients and health professionals alike the opportunity to assess clinical standards. This is a sensitive issue, and the full report looks at the results of publishing reoperation rates in Scotland following MAS of the prostate gland. These ranged from less than 0.5% to nearly 6.5%, but great care is needed in deciding whether real differences in clinical practice are indicated. Some argue that audit results should not be published until better performance measures are developed, but the key may be rather to ensure **they are**

not treated as league tables but used to identify areas where clinical care can be improved.

Implications for NHS Resources

A key question for NHS planners is what will be the impact of the spread of MAS. Some have suggested that as many as 50,000 **hospital beds** may not be needed by the year 2002. However, such forecasts are almost certainly too simplistic, and the full report notes that accurate projections are not possible at the present time. The DH sees such matters as surplus beds being resolved at local level by market forces. Some however, argue that there is greater role for strategic planning in this area, and **one option would be to develop some more detailed planning scenarios to try and narrow down the uncertainties involved.** Failure to develop a clearer picture could lead to premature bed closures with the attendant risks or, on the other hand, a failure to reap the maximum possible cost savings from the growth of MAS.

Another question is where best to **site MAS facilities**, and the full report looks at the case for dedicated units 'evolving' to meet demand within existing hospital departments, or special MAS units being built on hospital sites providing minimal access services across a wide range of surgical specialties. **Further analysis of the pros and cons of these options is needed**, since the siting of MAS facilities is strategically important and will affect the overall cost-effectiveness of the surgery provided. The increasing use of MAS is also likely to have significant implications for **primary health services**, particularly since discharging patients early switches the responsibility for continuing care and supervision away from hospital services and onto GPs, practice nurses, etc.

The Future

As described in this report, this is something of a critical period in the maturation of MAS. The first laparoscopic gall bladder removal in England was not conducted until February 1990, yet in the space of less than 5 years this procedure has become the method of choice, and at least 25,000 such operations are now conducted in the UK each year. Even the most conservative estimates suggest that MAS approaches will account for 40% of all operations - at least 2 million patients per year - by 2000. Yet while MAS has brought great benefits to many patients, this report identifies areas of potential concern, which argue for caution in managing future developments. In view of the large number of patients involved and the resource implications of MAS, this subject is likely to remain an issue of interest to Parliament and it is hoped that this analysis will assist in Parliament's consideration of the related issues.