ALSGBI comments on the report from the Aberdeen Health Technology Assessment Group

1. Clinical effectiveness:

The basis of the review was 19 RCTs of moderate quality. The strength of the evidence is good and we would agree with the main findings. However we believe that there are differences in quality of life between the 2 approaches.

A) Short-term outcomes

Summary:

- 1. Laparoscopic surgery is associated with a quicker recovery (in terms of length of hospital stay and return to normal activities), less post-operative pain and less blood loss. The duration of operation is longer. There is no difference in terms of adequacy of resection, mortality and complications.
- 2. Conversion rates significantly impact on the costs of laparoscopic procedures.
- 3. Quality of life. The review states (page 37, paragraph 3.3) that there is no difference in quality of life between the two approaches, although concedes that clinically important differences could not be ruled out.

Conversion rates:

- The review meta-analysis gives an overall conversion rate of 21%.
- There remains a question over quality control of the surgery, with many of the trials including surgeons who were still on their learning curve. It is thought that experience of 50 laparoscopic colorectal procedures is necessary to be adequately trained in the technique (Veldkamp et al, Surg Endosc, 2004). No trial stipulated that surgeons needed to have performed this number of procedures before entering patients.
- Therefore to a greater or lesser extent, experienced open surgeons were being compared to inexperienced laparoscopic surgeons.
- There is evidence from the CLASICC trial that conversion rates fall with increasing experience and from COST that duration of operation decreased with increasing numbers performed.

Comment:

There are many series reporting conversion rates as low as 5%, and we would contend that in experienced hands conversion rates will be significantly lower than 21%.

Quality of life:

- 3 out of the 4 trials that are included in the review favour the laparoscopic group with respect to QoL.
- There are differences in QoL up until 1 month post surgery. However the trials reported thus far have taken measurements of QoL only once or twice during this time (when the greatest benefits of laparoscopic surgery would be expected), and as such are not sensitive enough to demonstrate clinically important differences.
- The economic model used in the submission excludes short-term benefits. This is the time when the major impact and benefits of laparoscopic surgery would be seen.

Comment:

We believe that the limited evidence thus far does demonstrate QoL benefits for laparoscopic surgery in the first few weeks after surgery, but that more studies need to be undertaken to demonstrate the extent of these differences.

B) Long-term outcomes:

There are no differences in the 3 year outcomes with respect to overall mortality and disease-free survival.

2. Costs

There is a paucity of good quality data on costs following laparoscopic colorectal surgery.

The report concludes that laparoscopic resection is more costly to the health service by an estimated extra total cost of between £250 and £300. This represents a 5% difference between open and laparoscopic surgery, which could certainly be within the margin of error given the available evidence.

Of the 4 RCTs included in the review:

1) Two were from the far east, and their relevance to the UK could be limited.

2) Data from the COLOR trial (Janson et al) concludes that laparoscopic surgery is more expensive to the healthcare system; however the cost analysis they performed was "piggybacked" onto the COLOR trial; it included cost data from just one hospital with the results extrapolated onto the remaining patients; and COLOR included many surgeons who were still on their learning curve.

3) Cost data from the CLASICC trial has not yet been published; data from this trial is already between 5 and 10 years old, and included many surgeons on their learning curve.

4) The final study included in the review is that of King et al (BJS 2006). This is a relatively small study (62 patients in total), looking at the outcomes of laparoscopic and open colorectal surgery. However, they have performed a detailed economic analysis, and conclude that there were NO increased costs to the health service for laparoscopic surgery. The indirect costs of laparoscopic surgery were also lower for laparoscopic surgery, thus making the laparoscopic approach cheaper by £350 overall.

5) There are a number of non-randomised studies from experienced centres suggesting that laparoscopic surgery is cheaper to the healthcare system than open surgery (Senagore 2005, Salkfield 2004, Delaney 2003 & 2005, Shore 2003 etc)

Comment

We would contend that in experienced hands, with lower conversion rates and shorter hospital stays already being reported, the costs of laparoscopic surgery will be less than that of open surgery.

3. Cost effectiveness

The review concludes that there is a 40-50% chance that laparoscopic surgery is cost effective. We would draw attention to our comments above on costs, quality of life, and the lack of data from experienced centres.

Only a modest increase in QoL post-operatively (which measures thus far have been too crude to pick up), or a slight reduction in hospital costs (achievable from experienced units) would make laparoscopic surgery cost effective.

4. Training

- There are still relatively few surgeons performing these procedures, partly as a result of the previous NICE guidance.
- The ALSGBI and ACPGBI preceptorship programme has addressed concerns with regards to training in these laparoscopic techniques.

• As the preceptorship programme is under the auspices of the relevant surgical associations, uncontrolled and unregulated expansion of laparoscopic colorectal surgery would be prevented.

There are even fewer units with extensive experience (100+ cases). Results form these centres suggest that the encouraging results from the large trials previously reported can be improved on, resulting in better short-term outcomes (in terms of conversion rates, length of hospital stay) and lower hospital costs.

Conclusions:

- 1. There are no differences between laparoscopic and open surgery with respect to clinical effectiveness (both short & long term outcomes).
- 2. The RCTs examined in the review compare experienced open surgeons with inexperienced laparoscopic surgeons.
- 3. There is a paucity of good quality data on costs following laparoscopic colorectal surgery.
- 4. Despite this, the conclusions on costs and cost effectiveness of laparoscopic surgery show little difference to those of open surgery.
- 5. As units develop their expertise in laparoscopic surgery, short-term outcomes are likely to improve, making it more likely that laparoscopic surgery is cost effective.
- 6. Appropriate training is essential; we would advocate an increasing role for laparoscopic surgery, with its implementation under the guidance of the ALSGBI and its preceptorship programme.
- 7. Surgeons should start their learning curve with colonic procedures, moving on to rectal surgery with increasing experience.

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