First results after introduction of the four-armed da Vinci Surgical System in fully robotic laparoscopic cholecystectomy


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of a fully robotic laparoscopic cholecystectomy, using the da Vinci Surgical System, for the treatment of symptomatic cholecystolithiasis. This intervention was compared with manual laparoscopic cholecystectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing laparoscopic surgery for cholecystectomy were studied. The indication for cholecystectomy was symptomatic cholecystolithiasis, defined as one or more periods of colic pain in the right upper abdomen in the presence of cholelithiasis identified by ultrasound. The exclusion criterion was the presence of acute cholecystitis.

Setting
The setting was secondary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The effectiveness evidence and resource use data were collected for operations performed between 1 September 2003 and 1 February 2004. The price year was 2004.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The total study population was 24 patients. The study compared the first 12 consecutive patients undergoing fully robotic laparoscopic cholecystectomy with 12 control patients, matched for age and gender, undergoing a standard laparoscopic cholecystectomy in the same hospital during the same period. Power calculations were not reported. The authors stated that no specific criterion was used for selecting patients for fully robotic surgery, other than the availability of the da Vinci system and an experienced laparoscopic surgeon. The indication in 23 patients (96%) was symptomatic cholecystolithiasis without acute cholecystitis or previous biliary complications. The remaining patient
underwent cholecystectomy 4 months after a period of acute cholecystitis without cholestasis.

**Study design**

The study was a non-randomised trial that was conducted in a single centre. Follow-up was conducted at an outpatient clinic 2 weeks after surgery.

**Analysis of effectiveness**

The analysis of the study was conducted on an intention to treat basis. The primary end point of the study was operating time, which included preoperative anaesthesia induction time, preparation time and real operating time. In the robotic surgery group, real operating time was divided into operating time previous to robotic assistance, operating time with robotic assistance and wound closure time. The secondary end points of the study were operative complications and length of hospital stay.

Preoperative characteristics of the study groups were compared using statistical tests. There was a significant difference in the composition of the operating team. Specifically, robotic surgery patients were all operated on by an experienced general surgeon (although with limited experience of robotic cholecystectomy procedures, i.e. less than 3), while conventional surgery patients were operated on by a surgical resident in all but one case. The analysis investigated the correlation of previous robotic laparoscopic experience with several components of the total operating time, but found no statistically significant decrease in operating time due to learning curve effects.

**Effectiveness results**

The trial found that the duration of the overall operating room stay was significantly longer in the robotic cholecystectomy group than in the standard laparoscopic cholecystectomy group (2 hours 30 minutes versus 1 hour 59 minutes; p=0.042).

No significant differences were found between the groups in anaesthesia induction time, preparation time or real operating time, (p=0.28, p=0.76 and p=0.17, respectively).

The duration of hospital admission did not differ significantly (2.7 days for robotic patients versus 2.3 days for standard surgery patients; p=0.208).

Wound infection differed across the groups but failed to achieve statistical significance (25% for robotic patients versus 0% for standard surgery patients; p=0.064).

**Clinical conclusions**

The authors noted that a faster operating time in the robotic group had been expected, owing to the potential benefit of four-armed robotic assistance combined with the use of relatively experienced laparoscopic surgeons. However, the study showed that, despite improved three-dimensional optics, improved camera stability and increased dexterity, the use of robotics led to a significantly longer (31 minutes) operating time in this group. Secondary end points of hospital stay and perioperative complications found no differences between the groups. The authors attempted to provide potential explanations for the primary result, but admitted that no convincing benefits of robotic assistance were identified that could justify the increased consumption of time during laparoscopic cholecystectomy.

**Measure of benefits used in the economic analysis**

The cost and outcomes were left disaggregated. The authors therefore performed a cost-consequences analysis.

**Direct costs**

Discounting was not relevant given the short timeframe. The direct health care costs to the hospital were measured. The costs were for hospital stay, diagnostic tests, materials for laparoscopic cholecystectomy, accessories for sterile draping
and robotic instruments if applicable, salary (calculated on operating time), and outpatient clinic preoperative assessment and postoperative follow-up. The quantities and the costs were analysed separately, and their estimation was based on actual data collected prospectively during the study. The observed costs were not adjusted to correct for learning effects for new technologies because statistical testing had shown no correlation between experience with robotic procedures and total operating time. The price year was unclear. The total costs were reported.

Statistical analysis of costs
The costs were analysed using the Mann-Whitney U non-parametric test for independent samples.

Indirect Costs
No indirect costs were included.

Currency
Euro (EUR).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean total cost per patient was EUR 3,329 in the robotic surgery group versus EUR 2,148 in the standard surgery group, (p<0.001).

The mean incremental cost was EUR 1,181 per patient.

No statistically significant difference in any cost component was found (costs of hospital admission, outpatient clinics, accessories, diagnostics, operation theatre rent, materials used, salaries), so the result was driven by the cost of the robotic instruments (EUR 889 per patient).

No correlation was found between complications and costs.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The authors believed that robotic laparoscopic surgery provided multiple potential benefits over conventional laparoscopy. The study showed that robotic cholecystectomy was safe and feasible. However, the authors could find no convincing benefits of robotic assistance to justify the associated increased costs and increased operating time.

CRD COMMENTARY - Selection of comparators
The comparator (manual laparoscopic cholecystectomy) was explicitly justified as representing current practice in the authors' setting. The authors have also informed us that, in their opinion, "manual laparoscopic cholecystectomy has become the gold standard for patients suffering from symptomatic cholecystolithiasis". As a user of this database, you should decide whether the comparator represents current practice in your own setting.
Validity of estimate of measure of effectiveness
The study was intended to answer a hypothesis about the relative effectiveness of two treatments, so a randomised controlled trial might have been a more appropriate study design. However, the non-controlled allocation to the technology under study, together with matched controls, is a reasonable attempt to approximate a randomised design within the constraints of low patient numbers. The main cause for concern over the reliability of the study results was the significant difference across the two groups in the level of seniority and experience of the main operating clinicians, which appears to have been biased in favour of the robotic group. In addition, as no power calculations were performed, the study might have been underpowered to detect any statistical significance in specific health outcomes, such as operative complications. The study sample was representative of the stated study population and the patient groups were shown to be comparable at analysis. Appropriate statistical analyses were undertaken to establish potential biases, although no adjustments were made to the final results.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit and examined the costs and outcomes separately. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
All the categories of costs relevant to the hospital perspective were included. Relevant costs were included and were reported in the form of costs and quantities, separately, thus aiding reproducibility. The quantities of resource use were collected prospectively during the effectiveness study. The prices appear to have been taken from the authors’ hospital setting and so may have reflected charges rather than costs (e.g. operating theatre rent). No uncertainty in the costs or quantities was acknowledged or investigated. Although the study was based on a very small patient sample, the authors found statistically significant differences in the costs. Discounting was appropriately not carried out as the study had a short-term time horizon. The price year was 2004.

Other issues
The authors made appropriate comparison with findings from other studies, noting that their study was the first to evaluate fully robotic laparoscopic cholecystectomy with the da Vinci Surgical System. However it was not clear whether they intended this to mean that it was the first study to evaluate the procedure itself, or whether it was the first to evaluate the procedure using this specific robotic system. The issue of generalisability was not addressed. The authors did not present the results selectively and kept their conclusions within the scope of the study. The authors did not report any further limitations to their study.

Since this abstract was written the authors have provided us with the following clarification:

"...the use of a four-armed da Vinci robot enabled us to perform fully-robotic laparoscopic cholecystectomy instead of robot-assisted cholecystectomy. This allows surgery without the [need for] a table-side assistant, potentially reducing costs. To our knowledge, no previous study has been published, describing either the use of the four-armed robotic system, or the performance of the technique of fully-robotic laparoscopic cholecystectomy (as opposed to robot-assisted laparoscopic cholecystectomy)...."

Implications of the study
The authors concluded that robotic assistance was more likely to become cost-effective in complex procedures than in relatively simple procedures, where the advantages of improved optics and dexterity could translate to more technical possibilities, fewer complications and decreased time consumption. They recommended further research to identify those indications in which the benefits justify the time and costs.

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