High-level disinfection with 2% alkalinized glutaraldehyde solution for reuse of laparoscopic disposable plastic trocars

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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
High-level disinfection of laparoscopic disposable plastic trocars with 2% alkalinised glutaraldehyde solution.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of 30 female and 15 male patients who underwent laparoscopic cholecystectomy with the diagnosis of cholecystitis.

Setting
Clinic of Gastrointestinal Surgery, Turkiye Yuksek Ihtisas Hospital, Ankara, Turkey

Dates to which data relate
No dates for effectiveness, resource use or price data are specified.

Source of effectiveness data
The estimate of effectiveness was derived from a single study.

Link between effectiveness and cost data
The effectiveness results were estimated to be equivalent and a cost consequences analysis was performed retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
The sample consisted of 45 patients (15 male and 30 female with a mean age of 48 years). Patients were randomly allocated to the intervention group (n=30) and the control group (n=15), but no details were provided regarding the method of randomisation. No power calculations were performed to determine the sample size. Written informed consent for participation was obtained in all cases.

Study design
The study was a single-centre, randomised, controlled trial. The decision whether to use disinfected or disposable
trocars was made by a nurse but details of the criteria employed were not stated in the paper. The surgeons were blinded regarding the use of disinfected or new trocars.

**Analysis of effectiveness**
The primary health outcomes estimated in the study were identifications of organisms in: samples of glutaraldehyde, trocar, laparoscope, umbilicus, bile, peritoneal lavage fluid, epigastric incision and umbilical incision. Identification of organisms was performed by classical methods. The patients were asked, on the seventh postoperative day, to check the trocar access site for infection. Wounds were assessed according to Cruse’s criteria.

**Effectiveness results**
Gram-positive bacilli were isolated in one (3.3%) of the disinfected plastic trocars and in none of the new disposable trocars.

No culture positive results were found in the samples taken from laparoscope, glutaraldehyde, and epigastric incisions.

Culture positive results were obtained in 11 cases at the umbilicus (3 in the control group and 8 in the intervention group; non significant difference), in one case at the peritoneal lavage (in the control group) and in one case at the umbilical incision (in the control group).

None of the patients had infection at the wound site or intra-abdominally.

**Clinical conclusions**
Disposable plastic trocars subjected to high-level disinfection can be reused safely without infection risk, but the preventive precautions for patients should be observed.

**Measure of benefits used in the economic analysis**
The results from the effectiveness analysis for the intervention and control groups were considered equivalent and thus, a cost-minimisation analysis was performed.

**Direct costs**
The direct costs considered were the costs of new and disposable trocars, scissors, Veress needles, and clip appliers. Discounting was not relevant due to the short period of analysis (less than 1 year). The source of the cost data was not stated and costs and quantities were not reported separately.

**Statistical analysis of costs**
No statistical analysis was performed.

**Indirect Costs**
No indirect costs were considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.
Estimated benefits used in the economic analysis
A cost-minimisation analysis was performed after the effectiveness results for the intervention group were considered safe and without infection risks.

Cost results
The total costs, if disposable trocars were used, would have been $18,600. Instead only 8 trocars were used with an expenditure of $1,240, thus savings of $17,360 were realised. Additional $22,000 savings were realised by the reuse of scissors, Veress needles, and clip appliers. Thus the overall savings were $39,360.

Synthesis of costs and benefits
Costs and benefits were not combined due to the cost-minimisation approach adopted.

Authors’ conclusions
The authors concluded that disposable plastic trocars may be safely reused after high-level disinfection by 2% alkalinised glutaraldehyde solution, and that this is a very cost-effective method.

CRD COMMENTARY - Selection of comparators
The choice of new disposable trocars in the comparator group was suitable for the objectives of the study although a case for sterilisation with ethylene is a possible alternative. Users of the database should consider whether the comparator used is the proper alternative in their own setting.

Validity of estimate of measure of benefit
The lack of power calculation in determination of the sample size renders verification of the validity of the results difficult. In addition, concerns could be expressed regarding the selection of study participants (method not stated in the article) and the randomisation process of participants between the intervention and treatment arms.

Validity of estimate of costs
The article does not state whether the costs of disinfection (materials and labour employed) were included in the analysis. The quantities of resources were not separately reported. The case for realised cost savings is valid provided that the intervention is safe and without risk of infection. The lack of rigorous cost analysis that would have included statistical or sensitivity analysis and the lack of a price year do limit the generalisability of the cost results.

Other issues
The authors did make appropriate comparisons of their findings with those from other studies but did not address the issue of generalisability of the results to other settings and populations. The study sample appears to have been representative of the population considered.

Implications of the study
The study confirms the safety results of analysis of the use of disinfected trocars but the sample size may not have been sufficiently large to validate the conclusions.

Source of funding
None stated.

Bibliographic details

PubMedID
9533806

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Cholecystectomy, Laparoscopic /instrumentation; Cholecystitis /surgery; Disinfection /methods; Disposable Equipment /microbiology; Female; Glutaral; Humans; Male; Middle Aged; Prospective Studies; Surgical Instruments /microbiology

AccessionNumber
2199800484

Date bibliographic record published
31/05/2001

Date abstract record published
31/05/2001