Aspiration and sclerotherapy versus hydrocelectomy for treatment of hydroceles

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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
The study examined the effects of percutaneous aspiration followed by sclerotherapy, using tetradecylsulfate (STDS), compared to open hydrocelectomy in patients with symptomatic hydroceles. The aspiration of the hydrocele was performed using a 19-gauge butterfly needle. The aspirated hydrocele fluid was analysed in the laboratory to rule out infection, malignancy and spermatocele. Sclerotherapy was performed using a sclerosing solution consisting of a mixture of 4mL of 3% STDS, 6mL of 2% lidocaine hydrochloride, and 140mL of 5% dextrose in 0.45% normal saline. The volume instilled amounted to 25% of the aspirated hydrocele volume. All patients received prophylactic oral antibiotics after the treatment. To maintain the consistency of the technique, the treatment was performed by one of the investigators. Open hydrocelectomy was considered the current therapeutic standard and was performed by five staff urologists using either the Jaboulay method or the Lord technique.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis

Study population
The study sample was drawn from a population of patients visiting an urologist with symptomatic hydroceles. Since the effect of the sclerosing agent on fertility was unknown, patients still interested in reproduction were excluded. Furthermore, patients who had a current ipsilateral inguinal hernia, or coexisting scrotal pathology were excluded.

Setting
The setting was secondary care. The study was carried out in Kingston, Ontario, Canada.

Dates to which data relate
Effectiveness data for aspiration and sclerotherapy were taken from patients enrolled in the study between October 1998 and June 2000. Effectiveness data for hydrocelectomy were taken from patients who were treated at the same institution between December 1996 and August 1999. Resource use dates related to the same periods. The price year was not reported.

Source of effectiveness data
Effectiveness data were derived from a single study

Link between effectiveness and cost data
It appears that the costing was carried out retrospectively for each alternative treatment strategy. The authors did not link the cost information explicitly with the patients in each treatment group.
Study sample
Patients with hydroceles, diagnosed by scrotal ultrasonography, were included prospectively for the aspiration and sclerotherapy strategy. Information about the number of patients who were not eligible for the intervention, or who refused to participate in the study, was not given. The mean age was 64.6 years (range: 33 - 81). The control group consisted of patients treated previously with hydrocelectomy and was selected using data from the hospital. Mean age at time of surgery was 55.2 years (range: 28 - 71). Power calculations to determine the likelihood that differences would attain statistical significance were not reported.

Study design
A non-randomised controlled trial using a historical control group was carried out at the department of urology of a university hospital. 27 patients with a total of 28 hydroceles were included in the intervention group (aspiration and sclerotherapy). Loss to follow-up was 11% (3). The mean duration of follow-up was 8.9 months (range: 3 - 27). The control group consisted of 24 patients who had 25 hydroceles. Follow-up was available for all control group patients. Mean duration of follow-up was 6.4 months (range: 1 - 49).

Analysis of effectiveness
The analysis of effectiveness was based on treatment completers only. The primary outcomes were patient satisfaction and (procedural) success rates. Overall success was defined as patient satisfaction combined with cure (complete ultrasonographic disappearance of hydrocele). Success included complete patient satisfaction and a decrease greater than 50% in hydrocele maximum diameter. Partial success included complete patient satisfaction combined with a decrease of less than 50% in hydrocele maximum diameter. A patient was considered satisfied if the size and pain associated with the hydrocele decreased, if there was relief of any hydrocele-related disability and there was satisfaction with the overall experience and results. No further information was given about any specific method or instrument used to assess patient satisfaction. Complications were labelled as a secondary outcome of effectiveness. Baseline data including demographics and hydrocele data were presented for both patient groups. The mean age of the control group was lower than the intervention group.

Effectiveness results
Overall success rates were 76% (19) in the intervention group and 84% (21) in the control group.

36% (9) of the patients in the intervention group and 84% (21) in the control group were defined as cured.

In the intervention group an additional 16% (4) and 24% (6) was considered as a success and partial success respectively. For the control group this additional information was not available.

75% of the patients in the intervention group were considered satisfied compared to 87.5% of the patients in the control group.

Complication rates were 8% (2) in the intervention group and 42% (10) in the control group. In the intervention group complications consisted of edema (1 patient) and hematoma (1 patient).

In the control group 2 patients were found with edema, one patient suffered from both hematoma and wound infection, 4 patients had hematoma alone, one patient had a wound infection alone, and one patient was found with cellulitis.

Clinical conclusions
The authors stated that aspiration and sclerotherapy was considered as a reasonable first-line therapeutic option in the management of hydroceles, given that this procedure was simple, safe and reasonably effective and less costly than hydrocelectomy.
Measure of benefits used in the economic analysis
No summary measure of benefits was used in the economic analysis, the results being presented as a cost-consequences analysis.

Direct costs
The direct medical cost consisted of facility cost, cost of supplies, nursing cost, and urologist's and anaesthesiologist's fees. The costs of these components were presented per treatment procedure. Unit costs were not further specified, and no information was given about whether opportunity costs or charges were used. Furthermore, costs were not combined with the patients’ resource use in each treatment group. The costs of complications were not reported. Discounting was not performed. The authors did not report which price year was used to calculate cost.

Statistical analysis of costs
Costs were presented as point estimates. Statistical tests were not performed.

Indirect Costs
Indirect costs were not included.

Currency
Canadian dollars (Can$).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
The reader is referred to the effectiveness results reported previously.

Cost results
Cost results were limited to total cost per alternative procedure.

The total cost per aspiration and sclerotherapy procedure was $104.00.

The total cost per hydrocelectomy procedure was $905.00.

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

Authors’ conclusions
The authors stated that aspiration and sclerotherapy was considered as a reasonable first-line therapeutic option in the management of hydroceles given that this procedure was simple, safe and reasonably effective, and that it was less costly than hydrocelectomy.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator that was used. Hydrocelectomy was considered to be the current therapeutic standard in the treatment of hydroceles. You should decide if this is a widely used health technology in your own setting.
Validity of estimate of measure of effectiveness
The analysis was based on a non-randomised clinical trial using a historical control group. Since no information was provided about the number of patients eligible for inclusion in the study or the number of patients who refused to participate, it is not possible to assess whether the study sample was representative of the study population. The number of patients included in the study was relatively small, and power calculations were not performed. Patient groups appear to have been comparable except for age. The authors did not state whether this could have complicated the comparison. Results in the intervention group were based on treatment completers only and no statistical analyses were reported. Different degrees of effectiveness were used for the aspiration and sclerotherapy group. Finally, effectiveness data for patients in the control group were based on a longer follow-up period, a fact acknowledged by the authors. Given these limitations the internal validity of the results is likely to be low.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The study was therefore, in effect, a cost-consequences analysis.

Validity of estimate of costs
The authors did not explicitly state the perspective adopted for the study but it appears to have been that of the hospital. Total costs per alternative procedure were reported separately, but no further information was given about the sources or the methods used to calculate cost. Additionally, cost information concerning the separate parts of each procedure was limited.

Although the authors reported the amount of follow-up treatment procedures of patients in the intervention group who failed to respond to the initial treatment, this information was not further combined with costs. A relatively high number of patients in the intervention group needed additional treatment. Hence, the total cost of aspiration and sclerotherapy per patient was higher than the reported cost per procedure. Statistical analyses were not performed. No information was given about costs due to complications. The price year was not reported. Given these limitations the generalisability of the results is limited.

Other issues
The authors made appropriate comparisons of the effectiveness results for aspiration and sclerotherapy with those from other studies. However, no information was given about effectiveness data and complication rates of hydrocelectomy from other studies. This could have provided further evidence for the safety of aspiration and sclerotherapy in comparison to hydrocelectomy.

The authors discussed the limitations of the study in terms of the study design, the limited information about the patients treated with hydrocelectomy and the lack of long-term follow-up information about hydrocele recurrences.

The issue of the generalisability of the results to other settings was not addressed and the long-term implications of (partial) successes, such as the need for additional treatment in the future, were not discussed.

Implications of the study
The authors state that aspiration and sclerotherapy was considered as a reasonable first-line therapeutic option in the management of hydroceles given that this procedure was simple, safe and reasonable effective and less costly than hydrocelectomy. Given the limitations reported above, more research would be desirable to confirm the results presented in this study.

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