Lidocaine 2% gel versus plain lubricating gel for pain reduction during flexible cystoscopy: a meta-analysis of prospective, randomized, controlled trials

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CRD summary
The authors concluded that the evidence suggested that there was no statistically significant difference between lidocaine gel and plain gel lubrication in the reduction of pain in men during flexible cystoscopy. Given the absence of quality assessment, the presence of publication bias, variation in the included trials and the small evidence base, the authors' conclusions should be interpreted with caution.

Authors' objectives
To compare the effectiveness of 2% lidocaine versus plain lubricating gel for reducing pain in male patients during flexible cystoscopy.

Searching
PubMed and Scopus were searched for relevant trials between 1950 and September 2006, with no language restrictions. Some search terms were reported.

Study selection
Randomised controlled trials (RCTs) that compared the effectiveness of 2% lidocaine versus plain lubricating gel in reducing pain during flexible cystoscopy in male patients were eligible for inclusion. Eligible trials were required to assess pain using a 0 to 100mm visual analogue scale (0 denoted no pain and 100 denoted the worst pain possible). Cross-over trials and trials with missing data were excluded.

The men in included trials had a mean age that ranged from 57.3 to 69.9 years. Lidocaine and plain gel were administered in 10 or 20cc doses at five to 25 minutes prior to cystoscopy (where reported).

Two reviewers independently screened trials for inclusion.

Assessment of study quality
The authors did not state that they assessed trial validity.

Data extraction
Two reviewers independently extracted or calculated means and standard deviations (SDs) to estimate treatment effect sizes and standard errors using Hedge's adjusted g. Where estimates of the median or range of the visual analogue scale scores were not reported, the pooled standard deviation based on the other studies was used. Discrepancies were resolved by consensus.

Methods of synthesis
Effect sizes were pooled using a random-effects model, weighted by the inverse of the variance, to estimate summary effect sizes and 95% confidence intervals (CIs).

Statistical heterogeneity was assessed using the Cochran's Q test and I² statistic. Sensitivity analysis was performed by removing one trial at a time.

Publication bias was examined using funnel plots; where this was present, small sample bias was investigated by removing trials with less than 50 patients.

Results of the review
Seven RCTs (n=817 patients; range 39 to 172) were included in the review.
There was no statistically significant difference in mean pain reduction between patients receiving lidocaine gel and those receiving plain gel (seven RCTs). There was evidence of significant statistical heterogeneity ($I^2=77\%$). Sensitivity analyses, removing one trial at a time, resulted in a statistically significant difference in pain reduction between treatments when two trials were removed.

There was evidence of publication bias and removal of small sample trials did not significantly alter the results.

**Cost information**

One RCT reported the lidocaine gel was three times more expensive than plain gel in Taiwan. A second RCT reported that use of plain gel rather than lidocaine resulted in approximate savings of $5,000 in their institution.

**Authors' conclusions**

The evidence suggested that there was no statistically significant difference between lidocaine gel and plain gel lubrication in the reduction of pain in men during flexible cystoscopy.

**CRD commentary**

The review question was clear and was supported by appropriate inclusion criteria. The literature search was undertaken without language restrictions. However, as the search was limited to two databases, potentially relevant studies may have been missed; the authors acknowledged this. There was evidence of publication bias from the funnel plots. Screening of the studies and data extraction were undertaken in duplicate, which reduced the potential for bias.

The authors did not assess trial quality, which meant that the robustness of the findings was unclear. The authors acknowledged the paucity of data, with the evidence consisting of only a small number of trials with small sample sizes. Few patient details were reported, but details on treatment methods suggested methodological heterogeneity. There was also evidence of statistical heterogeneity; the source for this was not identified.

Given the limitations with the included trials and evidence of publication bias, the authors' conclusions should be interpreted with caution.

**Implications of the review for practice and research**

The authors did not state any implications for practice or research.

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