

Effects of intraurethral injection of anaesthetic gel for transurethral instrumentation

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INTRODUCTION

In current clinical practice, 2% lignocaine gel is widely used as a local anaesthetic lubricant before various forms of transurethral instrumentation (urethral catheterization, flexible or rigid cystoscopy, urethral dilatation) [1,2]. However, a controversial issue has been raised over the past few years about reported urethral discomfort when lignocaine gel is delivered [3,4]. Furthermore, clinical trials have questioned the efficacy of lignocaine gel for decreasing the pain perceived during cystoscopy [5,6].

DISCOMFORT DURING INTRAURETHRAL DELIVERY OF LOCAL ANAESTHETIC LUBRICANT

Thompson *et al.* [3] studied whether the temperature of lignocaine gel affects the perception of an initial discomfort during intraurethral delivery. In a prospective study, 60 men were randomized to receive lignocaine gel at 4 °C, 22 °C and 40 °C. After urethral instillation, patients had to mark their discomfort level by using a visual analogue scale (VAS). The authors found significantly less pain was perceived if lignocaine gel was used at 4 °C than at 22 °C or 40 °C, with no difference between the 22 °C and 40 °C groups.

Ho *et al.* [4] recruited 100 men scheduled for flexible cystoscopy in a double-blind, prospective study to test the hypothesis that plain aqueous gel causes less discomfort on delivery than lignocaine gel. Immediately after urethral delivery, patients were asked to quantify the associated discomfort using a VAS. Statistical analysis showed significantly less discomfort on delivery in patients

receiving plain aqueous gel than in those receiving lignocaine gel.

However, in both studies the authors admitted a lack of statistical power because there were too few subjects in each subgroup. Moreover, the delivery time of lignocaine gel is a critical issue for pain perception during flexible cystoscopy [7]. Injection with lignocaine gel over a period of 10 s causes significantly less urethral discomfort than delivering it over 2 s. The delivery time in the two cited studies was 2 s in [3] and 3 s in [4]. Furthermore, it remains unanswered if the discomfort on delivery of a lubricant before cystoscopy contributes a relevant share to the overall discomfort from the entire instrumentation, e.g. pain from cystoscopy.

ANAESTHETIC EFFICACY OF LOCAL ANAESTHETIC LUBRICANT IN FLEXIBLE AND RIGID CYSTOSCOPY

Several papers report studies of discomfort and pain during diagnostic cystoscopy [5,6,8–13]. In a prospective, randomized, double-blind study, Birch *et al.* [5] examined the discomfort of flexible cystoscopy in 138 men; 10 mL of 2% lignocaine gel or 10 mL of plain aqueous gel were injected into the urethra 10–15 min before cystoscopy. Pain perception was evaluated immediately after cystoscopy using a VAS. Overall, the study showed no significant difference in pain perception between the groups. Patients having their first cystoscopy had a higher pain perception when plain aqueous gel was used. Because there were few patients in the subgroups (lignocaine gel, 32; plain aqueous gel 22), the differences were not statistically significant.

Other studies of flexible cystoscopy in men, questioned the pain-reducing effect of lignocaine gel [8–10]. McFarlane *et al.* [8] randomized, in a double-blind, placebo-controlled trial, 60 men into three different groups, receiving 20 mL of placebo gel (group I), 10 mL of 2% lignocaine gel (group II) and

20 mL of 2% lignocaine gel (group III). Topical exposure over 15 min was secured by using a penile clamp. For pain perception there were no statistically significant differences among the three groups, with mean pain scores in groups I–III of 4.65, 3.93 and 3.57, respectively ($P = 0.406$).

In a randomized, double-blind study, Chen *et al.* [9] compared the pain-reducing effect of 20 mL 2% lignocaine gel (45 men) vs 20 mL plain aqueous gel (46 men) for flexible cystoscopy; the mean (SD) pain scores were similar in the two groups, at 2.8 (1.1) and 2.5 (1.1), respectively ($P = 0.06$). In addition, the demand for analgesics after cystoscopy was evaluated; in the lignocaine group, 12 of 45 patients requested analgesics after instrumentation, compared with six of 46 patients having plain aqueous gel ($P = 0.103$). Chen *et al.* [9] recommended studies with more patients, as the differences were not statistically significant.

Stein *et al.* [6] stratified 236 men and women into four subgroups in a prospective, randomized, double-blind study comparing lignocaine gel and plain aqueous gel, and intraurethral exposure times of 5 and 10 min before rigid cystoscopy. Pain scores measured by a VAS showed a significant difference between men and women (VAS score 3.3 vs 1.9; $P < 0.001$). Differences between the VAS scores of the subgroups receiving lignocaine or plain aqueous gel were not statistically significant (53 men, lignocaine, 3.2; 74 men, plain, 3.4; $P = 0.62$).

Goldfischer *et al.* [11] found, in a randomized, prospective, double-blind study, that lignocaine reduced pain during rigid cystoscopy; 179 men and women were randomized into two groups, receiving 30 mL lignocaine gel or plain aqueous gel, which were injected over 30 s and the urethra exposed for 20 min. There was no advantage of lignocaine gel over plain aqueous gel in reducing pain perception in women, but the pain scores for cystoscopy in men showed a

significant advantage for lignocaine gel vs plain aqueous gel.

VOLUME OF LOCAL ANAESTHETIC LUBRICANT

Brekkan *et al.* [12] assessed whether the volume of lignocaine gel applied influences the pain perceived during cystoscopy. In a randomized, double-blind prospective study 238 men and women were divided into two subgroups receiving either 11 mL or 20 mL of lignocaine gel. After cystoscopy, patients were asked to classify pain levels, using a VAS. No significant reduction in pain perception could be detected amongst the two groups of women. The men were stratified into two subgroups, aged >55 years or ≤55 years. There was a statistically significant pain reduction in patients aged ≤55 years who received 20 mL of lignocaine gel, but no difference between the subgroups of men aged >55 years.

EXPOSURE TIME OF LOCAL ANAESTHETIC LUBRICANT

Choong *et al.* [13] designed a prospective, randomized, double-blind study consisting of two consecutive parts to study whether the exposure time of lignocaine gel is relevant for pain reduction during flexible cystoscopy. In the first part of the study, 90 men were assigned to four groups receiving 20 mL of 2% lignocaine gel or plain aqueous gel over a 5- or 25-min exposure time. This study showed a significant difference in pain reduction for patients who received 2% lignocaine gel over an exposure time of 25 min compared with an exposure time of 5 min before endoscopy. Sixty men entered the second part of the study, to compare pain perception between exposure times of 15 min and 25 min; no difference was detected between these exposure times. The authors concluded that intraurethral delivery of 20 mL of 2% lignocaine gel over an exposure time of 15 min is to be preferred.

Stein *et al.* [6] found no difference in pain reduction before rigid cystoscopy after intraurethral exposure times of 5 and 10 min in the 'anaesthetic efficacy' study cited above. Eggersmann *et al.* [14] showed, in a randomized, double-blind, placebo-controlled study measuring sensory thresholds of the male urethra, that the pain-relieving effect

of lignocaine gel requires an exposure of >10 min.

SUMMARY

Five studies conclude that lignocaine gel has no effect on pain perception during cystoscopy [5,6,8–10]. The study of Birch *et al.* [5] evaluated pain perception only during flexible cystoscopy by an experienced urologist in 138 men. McFarlane *et al.* [8] studied pain perception in 60 men during flexible cystoscopy, with only 20 in each subgroup. Stein *et al.* [6] investigated pain perception during cystoscopy using a 17 F rigid cystoscope in 236 men and women in four subgroups. In two studies which showed pain reduction with lignocaine gel, 21 F rigid cystoscopes were used in 183 men [12] or 116 men [11].

Three studies focused on the discomfort during the delivery of lignocaine gel before instrumentation [3,4,7]. In two studies with rapid injection (delivery times 2 and 3 s), lignocaine gel caused more discomfort than aqueous gel [3,4], with one study showing less pain with a delivery time of 10 s rather than 2 s [7].

Thus clinical studies, which are capable of valid conclusions about the utility or otherwise of an anaesthetic in a gel preparation for transurethral instrumentation, must be sufficiently powered in the number of patients in the groups compared, and must fulfil certain criteria:

1. Pain or discomfort must be relevant to allow a measurable reduction; cystoscopy in women or flexible cystoscopy in men may not be adequate procedures to test pain reduction, as they generally involve low levels of pain or discomfort to start with.
2. As with each local anaesthetic, the exposure time before starting the instrumentation is crucial. A minimum of 10 min of exposure is required to develop the full anaesthetic efficacy [11,12,14].
3. The volume of anaesthetic gel is another important factor. In men, 20–30 mL of lignocaine gel seems to yield the best results [11–13].
4. Securing the topical exposure of the lignocaine gel to the urethral urothelium over

the required exposure time seems to be another important issue. It remains to be determined whether the use of a penile clamp is adequate in men and which strategy can be used in women.

5. The discomfort on delivery from an injection with a lubricant probably contributes a minor share to overall pain from a transurethral instrumentation. Rapid injection over 2–3 s causes more discomfort than a slow injection (10 s) [3,4,7].

In conclusion, the need to add an anaesthetic to a lubricant can be questioned for cystoscopy in women and if flexible cystoscopy is done by an experienced urologist. In men, a pain-relieving effect of lignocaine gel was reported for 21 F rigid cystoscopy. For reliable anaesthetic efficacy, larger volumes (20–30 mL) and longer urethral exposure times (≥10 min) must be used. Clearly, more studies are required to determine precisely the advantages and disadvantages of adding lignocaine to lubricants for urethral instrumentation, and indications for their use.

CONFLICT OF INTEREST

None declared.

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Abbreviations: VAS, visual analogue score.