

DISTRIBUTION OF GEL LUBRICANT FOLLOWING URETHRAL CATHETERIZATION IN AN ANIMAL MODEL

Hypothesis / aims of study

There are two common methods for lubricating intermittent catheters, hydrophilic coatings and gel lubricants. Each system has its strengths and weaknesses, although gel lubrication has been shown to provide similar lubricity to some catheters utilizing hydrophilic coatings, it has been hypothesized that the benefits of gel lubricants may be limited due to the lubricant not reaching the proximal urethra. This study was undertaken to test that hypothesis by visualizing the distribution of a commercially available lubricating gel following the insertion of the catheter in rabbits. The gel was labelled with a fluorescent material and its presence along the urinary tract was evaluated by qualitative assessment of presence of fluorescence on the tissue.

Study design, materials and methods

A saturated solution of Rhodamine B (Sigma Chemical) was prepared in deionized water and filtered to remove any undissolved particulates. The concentration of Rhodamine B was determined by evaporating triplicate samples of the filtered solution to dryness. A small aliquot of the Rhodamine B solution was added to the gel (Lubrajel RR, United-Guardian) yielding a final concentration of Rhodamine B in the gel of 0.06% by weight. The mixture was warmed in a 65°C oven for 1 hour and then mixed to homogeneity. The fluorescent gel mixture was transferred via syringe to fill individual catheter lubricant reservoirs.

Commercially available gel lubricated catheters were employed, and gel lubricant normally supplied was replaced by the fluorescent gel. It was determined that 8Ch catheters would be suitable for use in rabbits in the range from 4-6 kg. Prior to insertion, the catheters were lubricated by passing them through the gel reservoir in a manner consistent with normal usage.

Five healthy male New Zealand White rabbits weighing 4.3 to 5.5 kg were utilized for this study. Conditions of care and study were in conformance with the animal welfare guidelines (*Guide for the Care and Use of Laboratory Animals*, Institute for Laboratory Animal Research, National Academy of Sciences, 1996). Animals were individually housed in suspended stainless steel cages, and the room was maintained at 61-72° F with 30-70% relative humidity. The laboratory is an AAALAC internationally accredited facility and is registered with the US Department of Agriculture. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

Experimental Procedure

An intramuscular injection of a combination of ketamine hydrochloride/xylazine (34 mg/kg + 5 mg/kg) general anaesthetic was administered to each animal at a dose 0.6 ml/kg body weight. The perineal area was shaved, scrubbed with a germicidal soap, wiped with 70% alcohol and swabbed with povidone iodine. The animals were placed on isoflurane/oxygen for continued anaesthesia.

The prepuce was retracted from the penis and the penis was exposed. The catheter was prepared and inserted in a manner consistent with its clinical usage. The catheter was passed through the reservoir filled with Rhodamine B-labeled lubricating gel, inserted into the urethra and advanced approximately 8 cm (sometimes as far as 16 cm) to ensure that the tip had progressed into the bladder.

The catheter was immobilized by clamping to the distal urethra, and the animals were immediately euthanized by an intravenous injection of a sodium pentobarbital based drug. The urinary tract was carefully opened longitudinally leaving the catheter in situ. The urinary tract and catheter were examined under ultraviolet illumination and a qualitative assessment of the presence of gel was made. Photographs were taken under both normal room light and using ultraviolet light illumination.

Results

The study was observational in nature and a qualitative assessment was made of the presence of lubricating gel along the length of the catheter following insertion into the rabbit urinary bladder by way of the urethra. Under these conditions, fluorescence was observed along the length of the urethra, with a higher presence at the penile end and decreasing towards the bladder. A similar pattern was noted in all five animals. White light and the corresponding fluorescence photographs from one animal are presented in figures 1 and 2. The presence of fluorescent material was confirmed in a post-hoc image analysis of this photograph.



Fig. 1

Photograph of isolated bladder and urethra under visible (room) lighting

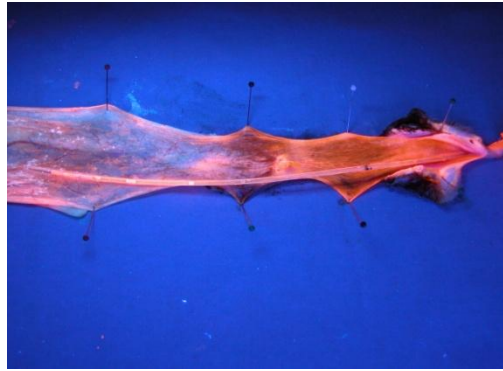


Fig 2

Corresponding photograph taken under ultraviolet light illumination

Interpretation of results

This limited study was designed to explore the presence of lubricant along the length of the urinary tract. Qualitatively, there was evidence of lubricant noted along the length of the urethra. Use of more sophisticated photographic techniques would improve the image capture and could allow better image analysis if quantification is needed. Any extrapolation from an animal model to human use must be done with caution.

Concluding message

It can be concluded that the lubricating gel deposited from the insertion of the catheter was present along the length of the urethra. While the results of this study do not directly address the possible issue of sufficiency of lubrication, they are consistent with the results of clinical studies where lubricity and urethral trauma were similar for the hydrophilic and gel lubricated catheters.

<i>Specify source of funding or grant</i>	Hollister Incorporated
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	ANIMAL
<i>Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained?</i>	Yes
<i>Name of ethics committee</i>	Animal Care and Use Committee