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Clinical reliability and cost analysis of using petroleum jelly creams versus water-based gels for urethral catheterization

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Abstract

Aim: Lubricants applied to the urethra prior to using the urethral catheter increase patient comfort and ease of operation. Different combinations of water-based lubricants are widely used in medicine. Combinations of fusidic acid and petroleum jelly creams and ointments are also used in the clinical routine for lubrication. In this study, we compared the use of a lidocaine gel (Cathejell®) and fusidic acid (Stafine®) cream containing petroleum jelly in urethral catheterization in terms of pain, cost and success rates.

Material and Methods: A total of 99 male patients who admitted to our clinic and were directed for urethral catheterization were included in the study. The patients were divided into two groups. Group 1 consisted of 36 patients who underwent urethral catheterizations after application of a cream containing fusidic acid (Stafine® cream 15gr) to the urethral meatus. In Group 2 (n=39), urethral catheterization was performed by squeezing lidocaine gel (Cathejell® lubricant gel, 12.5 g, single-use) to the urethra. Complications, visual analog scale scores, and weight of the medication spent were recorded.

Results: While the visual analog scale score in Group 1 was 3 (0-8), this value was 1 (0-4) in Group 2. No complications were observed in any of the patients. A cost analysis revealed that while fusidic acid (Stafine®) cream brought a cost of 0.27 $ per patient, the cost of lidocaine-containing gel (Cathejell®) was seven times higher.

Discussion: Although patients feel more pain, petroleum jelly based creams are safe and more economical to use in urethral catheterization of uncomplicated patients.

Keywords

Lidocaine; Lubricants; Fusidic acid; Petroleum jelly; Urethral catheterization; Visual analog scale; Cost

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Introduction

Insertion of urethral catheters is a procedure frequently performed in all hospitals. Urethral gels and creams are used to facilitate the insertion, provide ease of operation, and increase patient comfort [1]. Lubrication primarily protects the urethra from trauma and thus from the risk of development of stenosis. The use of 6 ml of lubricant in females and 11 ml in males has been shown to be sufficient for successful insertion of urethral catheters [1,2]. Although it has been reported that preventing traumas also decreases infections that may develop secondary to microtraumas and disruption of the integrity of the biofilm, information on this subject is insufficient [3–5]. Besides several procedures in urology, lubricants containing lidocaine can significantly reduce pain during the advancement of the catheter in the urethra, which is the most painful stage of urethral catheterization [6,7].

The lubricants currently offered in the market are generally in the form of water-based gels. This may be due to the fact that, unlike oil and petroleum-based lubricants, water-based gels do not interact with latex materials commonly used in medicine [8, 9]. Pure water-based gels, water-based gels with lidocaine, chlorhexidine, and lidocaine + chlorhexidine have been used in urethral catheter application for many years [12]. Apart from these, ear-nose-throat physicians have used solid petroleum jelly, water-based gels, and antibiotic-containing creams and ointments during Foley applications for epistaxis [13]. However, despite claims of some medical web pages, there is actually no data regarding the use of most of them in urology (available at: https://www.blowoutmedical.com/lubricant.html). Unfortunately, non-sterile liquids or solid petroleum jelly have been routinely used in the past and some antibiotic creams and ointments are still used now from time to time.

Lidocaine-containing gels are disposable and costly. On the other hand, antibiotic ointments and creams are less costly when calculated per patient and can be used to place catheters in dozens of patients. In this study, we aimed to compare a water-based polyacrylamide gel containing lidocaine and a petroleum jelly- based cream containing fusidic acid as lubricants during urethral catheterization in terms of cost, pain, and success of the procedure. The reader should be aware of the fact that this study does not aim to compare an antibiotic with a local anesthetic. We only used routine and widespread pharmaceutical products in this study.

Material and Methods

Ethics committee approval (2017-KAEK-189_2020.05.28_05) was obtained from the local ethics committee for data screening and analysis. A total of 99 male patients who underwent urethral catheterization in our outpatient clinic between January 1 and March 31, 2020, were included in the study. In this case-control study, the patients' data were obtained retrospectively from the outpatient records. Seventy-five patients who had indication for bladder catheterization (vesical globe, intermittent catheterization, urine tracking, bleeding) were included in the study. For standardization of the catheter diameter, only patients who underwent catheterizations with a 16F flat-tipped Foley catheter were evaluated. Group 1 consisted of 36 patients who underwent catheterization after a cream containing fusidic acid (Stafine® cream 15 g) was applied to the urethral meatus. Meanwhile, Group 2 consisted of 39 patients in whom urethral catheterization was performed by squeezing lidocaine gel (Cathejell® lubricant gel, 12.5 g single-use) to the urethra. As the waiting time is given as 5-10 minutes before the catheter insertion, the daily routine of our clinic, it is always waited for 5 minutes for the anesthetic effect of Cathejell® in. Patients with urethral stenosis, chronic catheter use, neurological disease, neurogenic bladder diagnosis, diabetic neuropathy, psychiatric illness, drug use, patients undergoing chronic pain treatment, and patients under the age of 18 years were excluded from the study. Moreover, patients in whom the initial catheterization attempt was unsuccessful and required additional manipulations were excluded from the study.

In Group 1, the used amount of Stafine® per patient was calculated after the tube ended. We divided the tubes' total Stafine amount (15 g) to the number of patients who had undergone catheterization using that tube. The cost per patient for Group 1 was calculated by multiplication the amount per patient and the dollar ($) currency at the date on which our hospital had bought the medical devices. The cost per patient for Group 2 was taken as the cost of a single Cathejell® product on the same date mentioned above.

The presence of any complications (unsuccessful attempt, hematuria or urethrorrhagia, rupture in the urethral wall, infection, urethral stricture, allergic reactions) developed during and after the procedure was investigated. The results of the visual analog scale (VAS), which is routinely used in our clinic to assess pain after interventional procedures, were also evaluated.

Statistical analyzes in the study were performed using the SPSS Statistics for Windows, v25.0 program (IBM Corp. Released 2017. Armonk, NY). The distributions were examined with the Kolmogorov-Smirnov test. The Mann-Whitney U test was used for non-parametrically distributed data, while the Chi-square test was used for categorical data. The statistical significance was accepted as $p < 0.05$.

Results

The mean age in Group 1 (n=36) and Group 2 (n = 39) was 70.31 ± 10.55 and 68.11 ± 13.72 years, respectively. There was no significant difference between the groups in terms of age ($p = 0.52$). Group 1 had significantly higher median VAS scores compared to Group 2 [3 (0-8) vs 1 (0-4), $p < 0.001$] (Table 1).

Table 1. Comparison of the groups in terms of VAS score and occurrence of any complications

	Group 1(n=36)	Group 2 (n=39)	p
VAS Score*	3 (0-8)	1 (0-4)	<0.001
Complications	0 (0)	0 (0)	N/A
Cost per patient ($)	0.27	1.91	N/A

VAS score was significantly higher in Group 1 compared to Group 2. Statistical analysis could not be performed because there were no complications in both groups. VAS: Visual analog scale; $p < 0.05$
* Data was expressed as "median (min-max)".

No complications were seen in any of the patients.

The cost analysis was performed for both procedures. Outpatient clinic supply receipt records were used to calculate the cost of the material used. It was determined that Cathejell® lidocaine gel was used at a rate of 12.5 g per patient, while for Stafine® that rate was 1.66 g per patient. Based on the pricing information obtained from the hospital pharmacy, Stafine®'s cost was 0.27 $ per patient, while Cathejell®'s cost was sevenfold higher.

Discussion

Multiple studies have evaluated lubricants containing local anesthetics in terms of pain scores. Chung et al. compared the lubricants containing lignocaine with water-based lubricants and found that lignocaine lubricants resulted in better pain management [12]. On the other hand, Tanabe et al. argued that neither catheter type nor lubricant type had any effect on pain scores during urethral catheterization [13]. Due to the lack of consensus on this subject, it is suggested that the use of standard lubricants is sufficient, except for patients with a history of urethral stricture [14]. However, when it comes to pain, it is also important to use the lubricant correctly in accordance with the recommendations of the manufacturer and to give enough time for the local anesthetic to take effect [14,15].

Despite this confusion in the literature, the use of lidocaine-containing lubricants has become the standard in clinical practice [4,14]. However, some medical centers warn of potential problems with the use of these materials. First of all, some studies cautioned about the systemic effects of lidocaine (NHS, Southern Health. Urinary Catheter Care Guidelines v5 SH CP 123., 2020.). In addition, although lidocaine-containing lubricants are effective in increasing patient comfort, their disadvantage is that they are quite expensive.

The data on the role of lubricants in the development of catheter-related infections are not consistent yet [3]. Some studies have reported that chlorhexidine added to lubricants to reduce catheter-related infections may cause allergic reactions in some patients [16].

In our study, we evaluated a gel containing lidocaine and a cream containing the antibiotic fusidic acid in terms of infection, complications, and pain. None of the patients had any complications, including infection. It is known that manipulation and technique are important when inserting the catheter [3]. Although there are no studies comparing water-based gels to petroleum jelly in terms of ease of operation, it can be thought that water-based gels can provide superior processing convenience due to their thicker consistency than petroleum jelly. However, in this study, we did not evaluate ease of operation, which is a subjective parameter. In terms of infection, since fusidic acid is an antibiotic, it can be thought that it should be superior to a gel without antibiotics. However, as stated in the literature, the aseptic technique alone can give very good results [1,3]. In this study, we also used aseptic techniques and did not observe any catheter-related infections even in patients that had undergone catheterization with water-based gels.

We also found that the VAS scores of patients using fusidic acid containing Stafine® were statistically higher than those using lidocaine gel Cathejell®. Our results were in line with other studies in the literature that had emphasized the superiority of lidocaine-containing gels in terms of pain control [7,10,12]. It should not be forgotten that enough time should be given after application of lidocaine gel for this effect to occur, and the main issue in studies that did not detect differences between various lubricants in terms of pain scores is perhaps due to non-compliance with the manufacturer's instructions for waiting times [1,13]. Although there was a significant difference in our study between those who used lidocaine gel and creams containing fusidic acid, no significant difference was observed in terms of clinical presentation of pain. Although the median VAS score in Group 1 was 3 (0-8), no significant clinical complaints were observed in the patients.

Creams containing fusidic acid also include petroleum jelly, glycerol and paraffin. Glycerol and paraffin are already included in many drugs applied to the mucosa or skin surface. On the other hand, there is no clear information on the application of petroleum jelly other than its topical use. It is mentioned in many package inserts and nursing guidelines as a suggestion that petroleum jelly should not be used in urethral catheterization (available at: https://www.nationwidechildrens.org/family-resources-education/health-wellness-and-safety-resources/helping-hands/catheterization-self-clean-intermittent-male). However, this is due to possible damage to the Foley catheter rather than to the body [9]. In 2004, Gaspar-Sobrinho FP et al. reported that petroleum jelly caused the Foley catheter balloons to rupture, but did not cause any degeneration in latex catheters [11]. Gels for topical use such as petroleum jelly are not considered harmful when refined according to the European Union standards and when polycyclic aromatic hydrocarbons that are associated with cancer are removed from their structure [17,18]. Medical petroleum gels are produced this way and are safely used in medical practice on the skin surface and nasal mucosa [11,19].

Although the price comparison of such a study may be altered due to several factors such as the economics of the countries, production rates, taxes, supply and demand equilibrium, the bidding process of that product, etc., we showed that lidocaine containing gel is sevenfold (1.6 $ per patient) costly than petroleum jelly in our hospital. This amount might seem small per patient; however, catheterization is a procedure which is performed very often in our hospital. Therefore, the cost of catheterization soars to large amounts.

To date, there have been no studies comparing petroleum jelly with polyacrylamide water-based lubricants. In this study, we demonstrated that fusidic acid creams containing petroleum jelly can be used easily and safely in urethral catheterization. Moreover, the use of such creams reduces the cost per patient up to 7 times (Table 1).

Limitations of the study include retrospective design and lack of long-term results due to the short study period. Also, localness is an important limitation for this study.

Conclusions

In this study, we have shown that a cream containing petroleum jelly combined with medical fusidic acid can be safely applied to the urethral mucosa. They do not have a negative effect on the urinary mucosa in the early period.

Lidocaine-containing gels provide better pain control than fusidic acid creams in urethral catheterization. However, there were no pain-related significant clinical complaints in either of the groups. The use of these two lubricants in urinary catheterizations was compared for the first time, and no complications or infections were observed in any of the patients. Creams containing petroleum jelly reduce the cost per patient up to 7 times. Therefore, we believe that the use of petroleum jelly based gels in urethral catheterization of uncomplicated patients is safe and economical, although patients feel more pain.

Scientific Responsibility Statement
The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement
All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest
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