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Toxic catheters and urethral strictures: A concern about types of catheters used in resource-poor countries

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Abstract
Various reports in the literature have confirmed urethral toxicity caused by the use of catheters, mostly latex catheters and their coated versions, resulting in long-segment urethral strictures or strictures located in multiple areas of the urethra. Most catheters used in resource-poor countries, such as Nigeria, are latex catheters with various coatings, such as silicone. The reasons for the widespread use of these potentially toxic catheters are mainly non-availability and/or the high cost of less toxic catheters. We report three cases of urethral strictures following the use of siliconized latex catheters in order to highlight the potential urethral toxicity associated with the use of latex catheters and to draw the authorities' attention to the need to regulate the types of catheters used in the country.

Introduction

Urethral toxicity from catheterization with certain types of urethral catheters is a well-known phenomenon in many developed countries. However, this problem has not received much attention in many developing nations like ours. There have been various reports from western nations highlighting toxicity from latex catheters, and some of these reports call for better catheter quality control [1,2]. The said toxicity has been related to the basic properties of the materials these catheters are made from. Latex catheters, which are the main type of catheters used in most resource-poor nations for their low costs, are the most implicated ones. Various types of catheters are in use. They are differentiated by the basic materials they are made of and the modifications of the basic materials through coating with more biocompatible materials and impregnation with antibiotics. However, silver alloy-coated Foley catheters, which were introduced to decrease the risk of catheter-associated urinary tract infections, may be associated with an increased risk of development of urethral stricture [3].

Latex catheters, the first type of catheters manufactured in the 1930s [4], are made of natural rubber produced by the rubber tree, a material which is organic and porous and which is composed of

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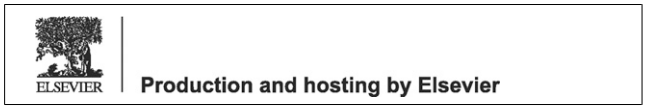

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polyisoprene rubber, water and low levels of different proteins. Latex rubber is most often obtained commercially from the sap of the Pará rubber tree (*Hevea brasiliensis*), named after the Brazilian state in which the plant was first discovered. Due to its natural source, latex rubber contains plant proteins which make it allergenic [5]. As latex is manufactured into products, chemicals are added to improve its properties. Because some of these additives are toxic, manufacturers attempt to remove them in the course of a leaching process, but some remain in the product. Chemicals in latex are toxic and can cause skin irritation, rash and allergic reactions.

Silicones are a group of synthetic polymers whose backbone is comprised of repeating silicon–oxygen bonds. In addition to their bonds with oxygen to form polymeric chains, the silicon atoms are also bonded to organic groups. They are one of the most thoroughly tested and most widely used groups of biomaterials and are well-known for their intrinsic biocompatibility and bio-durability. These key characteristics have been attributed to the material's inherent chemical and thermal stability, low surface tension and hydrophobicity. Silicones have been successfully applied in short- and long-dwelling catheters, drains, and shunts for over 60 years. They remain the materials of choice in many demanding applications [6].

Polyvinyl chloride (PVC) is prepared by the addition polymerization of vinyl chloride monomer. PVC is thermoplastic, although the pure polymer is hard and stiff. The addition of chemicals known as plasticizers is necessary to make PVC soft and flexible. These plasticizers, which can comprise a third by mass of the compounded plastic, are not chemically bound in the polymer molecules. As such, these additives can be extracted in vivo, causing several problems, one of them being induction of an acute inflammatory reaction to the leached plasticizer [7].

Apart from the basic properties of these catheter types, which are related to their biocompatibility, silicone catheters have been found to be superior to other catheters in terms of the period during which encrustation blocks the eyelets from deposition of calcium salt caused by the action of urease-producing bacteria. This benefit is also conferred on silicone-coated latex catheters [8]. Premature deflation of catheter balloons has been noted in 30% of latex catheters used for post-nasal packing as compared to nil for silicone catheters [9]. This means that there could be an increased need for repeated urethral catheterization, thereby increasing the cost of urethral catheterization and the risk of catheter-associated urinary tract infections (CAUTI) with latex catheters. Silicone is entirely biocompatible and rarely generates urethral epithelial inflammation, thus minimizing scar formation, and suture line contracture after urethroplasty.

Several reports of allergic reactions from latex materials have been reported by health care givers and patients, and there have been reports of urethral toxicity with the use of latex and coated latex catheters. Also, there have been concerns by the US FDA, as far as exposure to the PVC plasticizer DEHP (di(2)-ethylhexyl phthalate) is concerned. Exposure to DEHP has produced a range of adverse effects in laboratory animals, most notably liver toxicity and testicular atrophy. In view of these, the agency advised that "precautions should be taken to limit the exposure of the developing male to DEHP."

The paucity of publications on catheter toxicity seen in developing countries may be due to the fact that there are no opportunities for a comparison of catheters, as in most of these countries latex catheters constitute over 90% of catheters in use [10], and when there is toxicity resulting in urethral strictures, this may not be attributed to the catheters for lack of awareness of the possibility of toxicity from latex catheters. The urethral stricture may erroneously be attributed to either catheter-associated trauma or other factors. Whatever the situation, we have to face the problems caused by catheter toxicity.

In the following we report on three patients who developed strictures of varying degrees of stricture following the use of latex catheters.

Case reports

Case no. 1

A 27-year-old man was admitted to the medical ward on account of viral hepatitis complicated by encephalopathy. The patient was unconscious and was bedwetting, so an 18 Fr two-way siliconized latex urethral catheter with a balloon volume of 30 ml was placed. The passage of the catheter was uneventful and it was removed about 22 days later. About 7 weeks after catheter removal, the patient developed increasing difficulty in passing urine, which eventually progressed to acute urinary retention. After a failed attempt at urethral catheterization, the retention was relieved by suprapubic catheterization. The patient was subjected to retrograde urethrography which showed a long-segment stricture involving both the penile and bulbar urethra. He underwent urethroplasty using a circular penile fascio-cutaneous flap as onlay (Quartey flap). He subsequently did well, urinating with a good stream, though with some dorso-ventral chordee.

Case no. 2

A 63-year-old man had been suffering from lower urinary tract symptoms for one year, but without urethritis or urologic instrumentation. He was clinically fit, and digital rectal examination revealed a moderately enlarged prostate gland with benign features. Clinical examination and investigations confirmed the diagnosis of symptomatic benign prostatic hyperplasia (BPH). After a period of successful medical therapy he opted for surgery. He underwent open retropubic prostatectomy during which an adenoma weighing 80 g was enucleated and a 20 Fr well-lubricated two-way silicone-coated latex Foley urethral catheter with a 30–50 ml catheter balloon was passed. The immediate post-operative period was uneventful, and the urethral catheter was removed on the 6th post-operative day. The patient voided well until about 8 weeks after the operation, when he complained of splitting of the urinary stream with progression to a narrowed urinary stream. Retrograde urethrocystography (Fig. 1) revealed a long urethral stenosis and stricture in the mid-bulbar region. The patient had a crude catheter skin patch test by putting a piece of a sterile catheter of the same brand of the one used for catheterization on the volar aspect of the forearm. After about 48 h, the patient experienced intense discomfort and rashes on the skin in contact with the catheter. This was interpreted as an evidence of hypersensitivity. A better way of carrying out this test would have been the use of a sophisticated skin patch test, such as using eluates from catheters, to test for tissue toxicity [11]. The patient was subjected to urethral dilation done once to a gauge of 20/24 Fr with marginal improvement of the urinary stream. He subsequently went abroad for further treatment.

Fig. 1 Retrograde urethrogram showing extensive urethral stricture following urethral catheterization.

Case no. 3

The third patient was a 29-year-old transporter with a 5-month history of a moderate head injury from a road-traffic crash. He had sustained no associated chest, abdominal or pelvic injury. He was admitted and remained unconscious for days, during which an 18 Fr silicone-coated latex urethral catheter was passed on account of bedwetting. The catheter was left in situ for about 4 weeks. Eight weeks after removal of the urethral catheter, the patient noticed purulent urethral discharge and difficulty in passing urine. Since there was a progression of his urinary symptoms, he presented to the referring hospital. Attempts at urethral catheterization failed, and he was subjected to supra-pubic cystostomy to relieve the obstruction. Retrograde urethrography showed multiple annular partial strictures in the peno-bulbar region and penile urethra. Substitution urethroplasty was carried out, and the patient reported satisfactory voiding subsequently.

Discussion

Urethral catheters will continue to be an essential tool in the practising urologist's armamentarium. Since catheters were first manufactured in the 1930s, several modifications have taken place in order to eliminate the inadequacies (e.g. infection, encrustation, blockage and premature deflation of catheter balloons) which were encountered with the first types of catheters made of rubber or latex [4]. Studies aiming at the optimization of the biocompatibility of catheters and the reduction of biomaterial-related complications have resulted in the production of catheters made of more biocompatible materials, such as polyvinyl chloride (PVC) and silicone. Coating latex catheters with silicone, silver and hydrogel has also helped to reduce the incidence of complications encountered when using uncoated latex catheters, e.g. toxicity resulting from its antigenicity. Impregnation of catheters with antibiotics which are slowly released has helped to reduce incidences of catheter-associated urinary infections (CAUI). Newly developed catheters also glide more easily into the urethra with little or no friction [10]. However, many of these new types of catheters are more expensive than latex catheters. For this reason, it is the cheaper silicone-coated latex catheters that are available and affordable in many resource-poor countries, sometimes representing about 90% of the total number of catheters in use [10]. This explains why all the patients in this series were catheterized with silicone-coated catheters. However, silicone coating of latex catheters has been found not to be completely protective against the antigenicity of latex catheters, as the coating often breaks off, resulting in the latex being in direct contact with the urethral mucosa. In addition, there is not enough evidence to conclude that catheters with coatings offer greater protection than classical catheters and to recommend widespread use of coated latex catheters [12].

There is no doubt that the patients described in this case report developed urethral strictures after passing siliconized latex catheters, since there is evidence that none of them had urethral stricture before urethral catheterization. They all developed long-segment strictures involving the penile and bulbar urethra. Urethral strictures developing after prostatectomy are usually not as extensive.

It is important to emphasize catheter size. It is recommended that a 16 Fr catheter be used in adults when the indication is drainage of urine. However, when significant hematuria is expected in postoperative patients, a bigger catheter size, e.g. 20 Fr, will reduce the risk of catheter blockage due to blood clots, especially when the catheter is to remain in situ for a few days.

The crude skin patch test, though it may be faulted, may point to the fact that the hypersensitivity reaction noted in our patient may have been caused by catheter toxicity.

We conclude that catheter safety is an important issue to be considered by practitioners and authorities in developing countries. Cost effectiveness should be the consideration and not the immediate cost. In our environment, the cost of managing complications arising from urethral catheterization, such as urethral strictures, are usually very high and may be prohibitive, even when the expertise to perform the necessary procedures is available. Moreover, the costs of biocompatible catheters are usually negligible in the light of the overall cost of patient management.

Encouraging local production of biocompatible catheters may help to reduce considerably the cost of such catheters. In the meantime, while working towards having cheaper locally produced biocompatible catheters, the authorities should ensure that the available siliconized latex catheters are of high quality by preventing the import of poor-quality catheters. It is also important for practitioners to always reconsider the need for urethral catheterization especially when the indication is for the prevention of bed wetting.

The use of Paul's tube or condom catheters, which are appliances worn on the phallus like a condom, but with a tube at the tip through which a urine bag can be connected, should be considered.

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