«Air» in the urine drainage bag, for patients using uridomes.

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Abstract:

The objective of this study was to examine whether the amount of air in the urine drainage bag was reduced when using the new medical device, an applicator called ecinput, (Fig.1 green part), for connecting the urine drainage bag to the uridom.

A further objective for this invention was that the medical device should improve and secure the connection of the urine drainage bag tube to the sheaths, ***with no bacterial contamination***.

(Sheaths are a potential alternative for men with urinary incontinence who do not wish to use pads.
Sheaths are also called condom catheters, uridomes or external catheters, and are similar to contraceptive condoms.
They fit over the penis and are mostly "self-adhesive").

Fig.1

In this paper, the name uridome is used. Uridomes are usually connected to, and drained into, a drainage bag.

It is stated by observations from carers and nurses that after starting use of the ecinput applicator, the amount of "air" in the drainage bag, has significant decreased.

The conclusions, from the present literature study, are that the "air" is not really air, but gas produced by gas-producing bacteria. These bacteria have been introduced to the drainage bag during the, so far, common manual connection of the drainage bag tube into the uridome.

Background:

Urinary incontinence is extremely common, and is a symptom of the bladder's inability to properly store the urine.

The time used for manual connection of the draining tube to the uridome (Fig.1) can vary from 2 to 5-6 minutes. This can be really hard work with pushing, screwing and twisting. The work is performed in the intimate zone, and is uncomfortable and embarrassing for both the carers and the patients.

In (9) http://www.ecinput.no, is presented video instructions, as well as reports and other adequate information. (Unfortunately, in Norwegian only).

The traditional manual connection also results in a significant temperature increase due to

friction during the connection work. This increase in temperature (see report on www.ecinput.no), may trigger the growth of bacteria which might have been introduced from the carers gloves onto the drainage tube. The bacteria may originate from the patient's own bacteria flora, transferred by the carers.

Tests performed at the Teknologisk Institutt (National Institute of Technology) in Oslo have shown that the temperature measured on the connection point (thermophoto) after 3 minutes manual work had a temperature rise of 17 ºC (24-41 ºC) when the traditional manual method is used.

When using the ecinput applicator, the connection time is less than 1 minute, typically 20-30 seconds. ***There is no temperature rise or bacterial contamination***.

The ecinput applicator can also be used for indwelling catheters.

Interviews with patients (and carers) have revealed that the carers often have none or deficient education in healthcare. They may be students or people without training. They are not very carefully with changing gloves after washing the patient's abdomen before changing the urine drainage bag. In the Norwegian newspaper Aftenposten (30 August 2013) is reported that 28% of the carers working in homes, are none- educated.

Most carers should have had a minimum of advice on how to apply uridomes correctly as well as the connection technique when changing and connecting to the urine drainage bag with the lowest possible contamination.

The uridome users are men with all kinds of reduced urinary functionality (incontinence). Several of them may need help for application and change of the applicator, whilst others have some functionality in their hands and may be able to change by help of the ecinput applicator.

If the drainage tube is not properly connected to the uridome, twisting the uridome tube may be the result. This will stop the urine flow into the bag and a blowout is the fact.

The bacteria concentrated on the urine drainage bag tube will by manual handling, be transported into the uridome tube and be rubbed upwards toward the penis. Some uridome tubes can be damaged on the inside walls and others contain talc or glue. Mixed with urine this will create an excellent place for bacterial growth.

It is stated that among others, *Staphylococcus epidermis*, which is the most common bacteria for the intestines, can produce a mucus layer which can be fixed to various materials (e.g. plastic).

The bacteria can come from:

- The patient's own intestinal flora (endogen infection)
- Transferred by contaminated equipment (exogen infection)

By increased temperature within a certain area, the rate of chemical and enzymatic reactions,

are increased and the bacterial growth will speed up.

If the bacteria have been pushed upwards to the end of the drainage tube, it is a very short distance to the urinary tract opening (urethra) and further up to upper tract (uretre). Urine may accumulate in this space. This urine reservoir can be site for bacterial growth.

The bacteria can lead to urinary tract infection (UTI), which probably affects about one-half of all people during their lifetimes. Men with incontinent using pads are overrepresented. Those using ecinput applicator, have significant fewer cases of UTI.

Observations:

It has been claimed from carers and nurses that it is far less "air" in the urine drainage bag after they started using the ecinput applicator.

Some patient also claims that the back pressure when urination, is significant reduced.

By the end of the urination, the pressure from the urine- bladder is lower than backpressure from the urine drainage bag. The patient has to "push" to let the last drops out. The backpressure results in a volume of urine that stays in the tube. Bacteria remains in the reservoir and an infection (UTI) may start.

The bacteria which has come with the urine flow into the urine drainage bag is suspected to give what is called "air" in the bag, by gas-formation. Normal air has no access to the bag.

Theory:

The theory, which may be confirmed through this literature investigation, is that far more bacteria are transferred into the urine drainage bag by the traditional manual coupling, than when using ecinput applicator. Those bacteria are gas-producing (ammonia and carbon dioxide), which results in "gas" in the bag by the hydrolysis of urea.

Normally content of urea in urine is about 2% (1).

Urine:

Urine is a solution of organic and inorganic compound (1) which secretes via the kidney. 95% of the content is water. The urine volume secreted is 1-1.5 liter per day. The volume vary a lot, due to different water-consume, illness and heavy evaporation from the body.

The urine volume increases by *diabetes mellitus* because the sugar in the urine will withdraw larger volumes of water by osmosis, then the urine production is increased.

Diabetes-patients using uridomes have more often UTI caused by bacteria infected urine retained in the uridome tube by backpressure and full bag.

Urine's solid compounds:

Urea is a nitrogen containing compound that is produced during decarboxylation of the amino acid arginine in the urea cycle. Urea is highly soluble in water, and is thereby an efficient way for the human body to discharge excess nitrogen. Urea is a waste product excreted in the urine by animals.

The daily production of solid materials in the urine is 35-60 grams. (1).About 60% is nitrogen- containing organic waste: urea (15-30g), uric acid (0.5-1g) and creatinine (1-2g).

In addition are: sodium, potassium, chlorine, calcium, phosphates and sulphates.

Ammonia (0.5-2) g is a base formed in the kidney. When urine is stored, it starts smelling ammonia. This is a result from that the bacteria in the urine splits the urea molecule into carbon dioxide and ammonia.

$(NH_2)_2CO + 2H_2O \rightarrow CO_2 + H_2O + 2NH_3$

Urease:

Urease is a hydrolytic enzyme that attacks the nitrogen and carbon bond in amide compounds such as urea and forms the alkaline end product ammonia. More specifically, urease catalyzes the hydrolysis of urea to ammonia and carbamate; the carbamate produced is subsequently degraded by spontaneous hydrolysis to produce another ammonia and carbonic acid (3, 4, 8).

Some bacteria produce urease very fast, whereas others need more time. Others do not produce urease at all.

Some of the bacteria producing urease need a small amount of the substance which to be split (named substrate) present, to get the production of urease to start. This is called enzymatic induction (5).

Urease is produced of several bacteria, including normal flora and non-pathogen bacteria (6).

Enzymes and environmental dependence:

Enzymes are catalyst, which in chemical matters is a substance, participating a process and increase the rate without self being consumed (5).

Biological catalysts are far more specific than inorganic catalysts. That means, they do not catalyze reactions in general, but have specific scopes.

Some enzymes are so specific that they only can catalyze *one* particular reaction in one type of molecule. As an example, the enzyme urease has no other purpose than split urea into

ammonia and carbon dioxide. This is known as “substrate specific enzyme”.

Enzymes are very temperature sensitive. Their effectivity increase by rising temperature up to approximately 40ºC where they start denaturation (changing). Generally we can suspect that enzymes in human body acts best at 37ºC.

The temperature by manual connection method increases from RT (room temperature) to 41ºC in a very short time. (see report www.ecinput.no). And plastic/silicone stays at the higher temperature for a certain time, before decreasing to RT.

When using ecinput applicator, there is no temperature rise at all.

Gass producing bacteria:

Urease producing bacteria is producing gas (7).

The most common are: (4)

- *Proteus mirabilis* and *Proteus vulgaris*
- *Ureaplasma urealyticum*, a relative of *Mycoplasma spp.*
- *Nocrdia*
- *Campylobacter ureolyticus*
- *Cryptococcu*s spp.
- *Helicobacter pylori*
- Enteric bacterier inkl. *Proteus* spp., *Klebsiella* spp., *Morganella, Prividencia, Serriata* spp, *Brucella*
- *Staphylococcus saprophyticus*
- *Pseudomonas*
- *E.coli*

It has up to now, been discussed if *E.coli* is producing urease. Several research groups *have performed a lot investigation* in that area, and have reached the conclusion that at least 2 or 3 *E.coli* strains produce urease (8).

Discussion:

It is here shown that the great amount of gas (air) occurring in the urine drainage bag, most probably comes from gas formed by the bacteria which has come into the urine drainage bag. The bacteria can be of various types, including the patient’s own bacterial flora, often via the carers handling and bad habits. The probability of bacterial contamination is significant when using the traditional manual connection of urine drainage bag tube to the uridome.

This bacteria contamination is eliminated when using the ecinput applicator.

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