

A Summary of Experience and Observations of the Prospective Multicenter Clinical Trial of the Modular Built Medical Device whose Purpose is Delivering Medical Solutions into the Female Bladder in the Form of Self-Treatment; Second Arm

Highlights of the Hungarian Document

The information we have collected, the things have changed and the progresses we have made since then are inserted in the form of footnotes.

The trial was permitted by the National Institute of Pharmacy and Nutrition, Hungary.
Register number: OGYÉI/32949/2018.

Place of trial (second arm): Rózsakert Medical Center, Budapest, Hungary

Leader of trial: Prof. Sándor Lovász

Objective: A tryout on the medical device to enable self-instillation. The device has been developed according to the application for government and EU Fund GINOP-2.1.7-15. Assessing the usability, the benefits, the possible side effects of the device, collecting the patients' opinions and suggestions to be able to make further developments on the prototype and examining the efficacy of MID-ii U.S.A.^{®1} as a device for catheter-free bladder instillation.

In this arm of the trial there were 15 patients first with the condition of interstitial cystitis/bladder pain syndrome (IC/BPS), their mean age was 39.5 years (27–63 years).

According to the end-of-trial questionnaire given to the patients, the following conclusions can be drawn.²

All the patients were able to learn how to use the device and how to document their experience and get all legal documents signed. To complete this task, we needed two occasions to meet, and spending with them maximum 100 minutes were sufficient. Further instillations performed at their homes greatly helped in learning the precise and safe handling of the device. Temporarily, which means the first couple of attempts; the assistance of a relative was necessary for some of them.

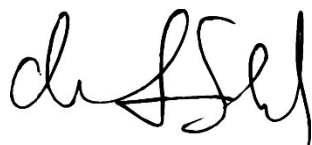
The biggest issue was the pumping up of the components of the medical solution from different vials with the syringe. This suggests us the necessity of using ready-to-use, pre-filled syringes.³

Most of the patients pointed out that observing the magnified, well-lit, shadow-free image of the camera helps the self-treatment significantly. On 3 occasions the LED lights did not provide sufficient illumination, on 1 occasion the image of the camera was blurred. According to these feedbacks a stricter quality control of the cameras will be essential.⁴

13 patients emphasized that the administration of the medicine with MID-ii U.S.A.[®] was entirely painless and finding the urethra was easier, too. 70% of the patients reported leakage,

its amount was considerable at the first two occasions of self-treatment, but later it decreased gradually. It must be taught thoroughly how the leakage can be prevented.⁵

All of the 15 patients stated that they would like to keep the device and use it for self-instillation in the future. They would recommend the device others, too. The patients expressed that they would continue the therapy under medical supervision, by informing their therapists about their condition on the internet and via phone calls. Personal visits would take place in every 6 months, at these occasions the technical condition of the device would be examined, the instrument would be a subject of maintenance and occasional updates, too.



Dr. Lovász Sándor

Rózsakert Medical Center

19th Nov. 2018

Comments

All the 15 patients who were participating informed us that they are content with the device, they would like to keep it and use it regularly in the future.

The teaching session consisted of (1) a demonstration about the device, its elements and its assembling, which lasted for 1.5–2 hours and (2) another occasion when the patients performed self-instillation under the supervision of the therapist, which lasted for 45–60 minutes.⁶ Later they performed self-instillation at their homes, on their own.

6 patients reported some leakage whose amount became gradually smaller during the forthcoming self-treatments. Finally, its amount was negligible. 8 patients reported considerable leakage and its amount become smaller from instillation to instillation. 1 patient left the country and received her medicine later. During the two self-treatments she performed there was no significant leakage.⁷

5 patients had temporal urethral pain after the first 2–3 treatments. Later they became more relaxed, which lead to the cease of pain. No patient reported long-lasting pain, nor blood in the urine.

4 patients noted that pumping up the several solutions is problematic, since none of them had used a syringe before. All patients suggested using pre-filled syringes.

There was no urinary tract infection of clinical significance reported.

All of the patients had had a treatment before where MID-ii U.S.A.[®] had been applied. They considered it a benefit that they did not have to travel to visit the therapist, pay the fee of the therapy, nor arrange some time for the visit. 9 patients pointed out that they would be able to

treat themselves whenever it was necessary. 3 patients told there was a psychological benefit of the device as well, since they felt less dependent on their therapist.

Personal feedbacks from patients of the test group:

“It would be helpful if there were an informative video about the self-instillation.”⁸

„In order to learn to use the device I would recommend bigger syringes”.⁹

„It would be useful if it were explained how to pump up the solutions. It is hard for those who are not working in the healthcare. Besides the size of the syringe, the size of the needle should be told us, too. Not every type of needle can be used for the process. [...] If there is no relative present during the learning period, there should be ready-to-use syringes given.”¹⁰

“No doubt it is much more comfortable and, obviously, pain-free to use the self-treating device instead of a catheter. At this point I am quite good at finding my orifice [...], but I need to practice to perform the instillation with no leakage.”

“It is life-saver for me to have the self-instillation device with me all the time! Even if I don’t need to be treated for a while, it makes me calm that I would be able to treat myself if I really had to. I can hardly wait for the serial product; I’ll definitely buy it as soon as it’s out.”

1 At that time, the device you know as iAluadapter was called MID-ii U.S.A. ®. Our current name of it is UroDapter®.

2 A follow-up questionnaire after one year experience with the device is being performed currently.

3 In the trial there were no pre-filled syringes used. However, iAluRil® is sold and packed together with iAluadapter® in a ready-to-use form, which alone overcomes the biggest issue we experienced during the trial. The cocktail, which was used at that time needed to be assembled by the patients. Now it is packed and dosed for self-instillation by a pharmacy.

4 Regarding quality control, we have found a new model whose specifications match the needs. Its quality is being monitored constantly. Also, according to the later tests, the external illumination affects the quality of the image can be seen on the display. This is explained in the User’s Manual, too.

5 In the majority of cases leakage occurs because (1) too low or too high pressure is applied with the UroDapter® (and the syringe), or (2) the angle of the instillation is wrong. The User’s Manual of UroStill® elaborates both situations. The topic is covered in a more detailed form in the guide for using UroDapter®, which has been written for therapists.

6 Regarding the User’s Manual, its illustrations, the experience has been gained so far and will be gained in the future as UroStill® is being better known than it is currently, this amount of time shall be significantly smaller. Due to the previously mentioned factors, even if UroStill® is a device which has to be used according to the guidance of a therapist, performing self-instillation with it may be possible without any personal educating session.

7 See footnote (4) about leakage.

8 The first footage on the topic is already available on our webpage: www.urosistem.com

9 UroStill® can be used with both 20ml and 50ml syringes. Luckily, iAluRil®'s prefilled version is the latter one.

10 See footnote (2) about the topic.