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A plain language summary of the LOCK IT-100 study of taurolidine/heparin catheter lock solution and catheter-related bloodstream infection in hemodialysis

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Plain Language Summary of Publication



Future MICROBIOLOGY

A plain language summary of the LOCK IT-100 study of taurolidine/heparin catheter lock solution and catheter-related bloodstream infection in hemodialysis

Anil K. Agarwal[a], Jared Crandon[b], Elizabeth Hurlburt[b], Mary Michaud[b], Antony Pfaffle[b], Prabir Roy-Chaudhury[c,d], Celina Medina[e], Paul T. Conway[f] & Edward V. Hickey III[f]

[a]Department of Medicine, University of California San Francisco, CA, USA; [b]CorMedix Inc., Berkeley Heights, NJ, USA; [c]University of North Carolina Kidney Center, Chapel Hill, NC, USA; [d]WG (Bill) Hefner Veterans Affairs Medical Center, Salisbury, NC, USA; [e]Patient Author (Kidney Patient Advocate), Long Beach, CA, USA; [f]American Association of Kidney Patients, Tampa, FL, USA

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Where can I find the original article on which this summary is based?

The original article titled 'Taurolidine/Heparin Lock Solution and Catheter-Related Bloodstream Infection in Hemodialysis: A Randomized, Double-Blind, Active-Control, Phase 3 Study' was published in the *Clinical Journal of the American Society of Nephrology*, a journal widely read by kidney doctors (nephrologists) and kidney patient advocates. You can read the article for free at: https://journals.lww.com/cjasn/fulltext/2023/11000/taurolidine_heparin_lock_solution_and.11.aspx

Summary

What is this summary about?

This is a plain language summary of an article originally published in the *Clinical Journal of the American Society of Nephrology* about the LOCK IT-100 study. The purpose of the LOCK IT-100 study was to find out if the taurolidine/heparin catheter lock solution can help prevent catheter-related bloodstream infections, which can be serious or deadly, in patients with kidney disease who are receiving hemodialysis (blood dialysis) through a central venous catheter (CVC), which is a long, flexible tube made of medical-grade polyurethane or silicone that is inserted into a large vein. Hemodialysis refers to a process that eliminates waste products, toxins, and excess fluids from the blood when the kidneys do not work properly (kidney failure). Catheter lock solutions are put into the catheter in between dialysis sessions when the catheter is not in use. The solutions typically contain a blood thinner, such as heparin, to prevent blood clots from forming and blocking the catheter.

The taurolidine/heparin catheter lock solution, in addition to heparin, contains a unique antimicrobial drug to prevent bacteria and fungi from living in the catheter, where they may cause an infection by spreading to the bloodstream. These catheter-related bloodstream infections are a deadly complication in some patients receiving hemodialysis through a catheter. The LOCK IT-100 study compared the taurolidine/heparin catheter lock solution with another catheter lock solution that contained heparin alone, which helped study researchers to find out if the taurolidine/heparin catheter lock solution was more effective in reducing the risk of these catheter-related bloodstream infections.

How to say...

- **Arteriovenous:** ar-teer-ee-oh-VEE-nuhs
- **Fistula:** FIS-chuh-luh
- **Gentamicin:** jen-tuh-MAHY-sin
- **Hemodialysis:** hee-mow-die-AL-uh-sus
- **Heparin:** HEH-pr-uhn
- **Hyperkalemia:** hai-PER-kuh-LEE-mee-uh
- **Hypertension:** hai-PER-TEN-shuhn
- **Infarction:** in-FARK-shuhn
- **Myocardial:** mai-oh-KAR-dee-al
- **Pneumonia:** nuh-MOH-nyuh
- **Sepsis:** SEP-sis
- **Systolic:** si-STOHL-ik
- **Taurine:** TAW-reen
- **Taurolidine:** taw-RAW-li-deen
- **Vancomycin:** VAN-ko-MAHY-sin
- **Venous:** VEE-nuhs

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What were the key results?
Nine out of 397 (2%) people who received the taurolidine/heparin catheter lock solution developed a catheter-related bloodstream infection compared with 32 out of 398 (8%) people who received the heparin catheter lock solution. The risk of developing a catheter-related bloodstream infection was reduced by 71% in people who received the taurolidine/heparin catheter lock solution compared with those who received heparin alone. Side effects were similar in the taurolidine/heparin and heparin groups. The most common serious side effects in both groups included pneumonia, fluid overload, and sepsis. Serious side effects are those that may have severe or life-threatening outcomes and may require hospitalization or medical treatment.

What do the results mean?
Patients receiving hemodialysis through a CVC were less likely to develop a catheter-related bloodstream infection with the use of the taurolidine/heparin catheter lock solution than with the use of heparin alone. There were no safety concerns, meaning no potential harm or risk to participants in the study, related to the taurolidine/heparin catheter lock solution. These findings could help to inform patients with kidney disease and health care providers when making decisions about hemodialysis treatment.

What is the purpose of this plain language summary?

The purpose of this plain language summary is to help you understand the findings from recent research. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study.

Who should read this article?

This summary of the LOCK IT-100 study results is intended for:

- People who need hemodialysis
- Caregivers of people with kidney disease who are receiving hemodialysis
- Health care professionals (such as doctors, physician assistants, nurses, nurse practitioners, and patient care technicians) who treat and care for people with kidney disease
- Public officials, government leaders, and organizations for patient advocates and health professionals involved in policy and educational initiatives related to infection prevention across the kidney disease population

Who sponsored the study?

This study was **sponsored** by CorMedix Inc.

Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

What is hemodialysis?

The kidneys are 2 organs in the body that filter blood, control the body's fluid balance, and remove waste products and toxins from the bloodstream. Patients whose kidneys are no longer functioning properly (kidney failure) may require **hemodialysis** treatment to remove waste and extra fluid from their blood.

Hemodialysis: A process through which waste products, toxins, and excess fluids are removed from the blood when the kidneys do not work properly (kidney failure).

Vein: Blood vessel that carries oxygen-poor blood from the body back to the heart.

Kidney dialysis has been available since 1943, when the Dutch physician Willem Kolff invented the first dialysis machine, which was further improved upon by Dr. Belding Scribner. During a hemodialysis session, the patient has a tube attached to one of their **veins**. Blood from the patient is circulated into a dialysis machine via the tube where it is cleaned and then returned to the patient through another separate tube. Cleaning the blood refers to removing urea (a waste product from protein breakdown), excess potassium and other elements, and excess water that have accumulated because the kidneys are not working. Hemodialysis generally takes 3 to 4 hours and is done about 3 times a week. The majority of patients receive hemodialysis at a dialysis treatment center, which is a facility where multiple patients go for dialysis, while a small minority can receive dialysis at home.

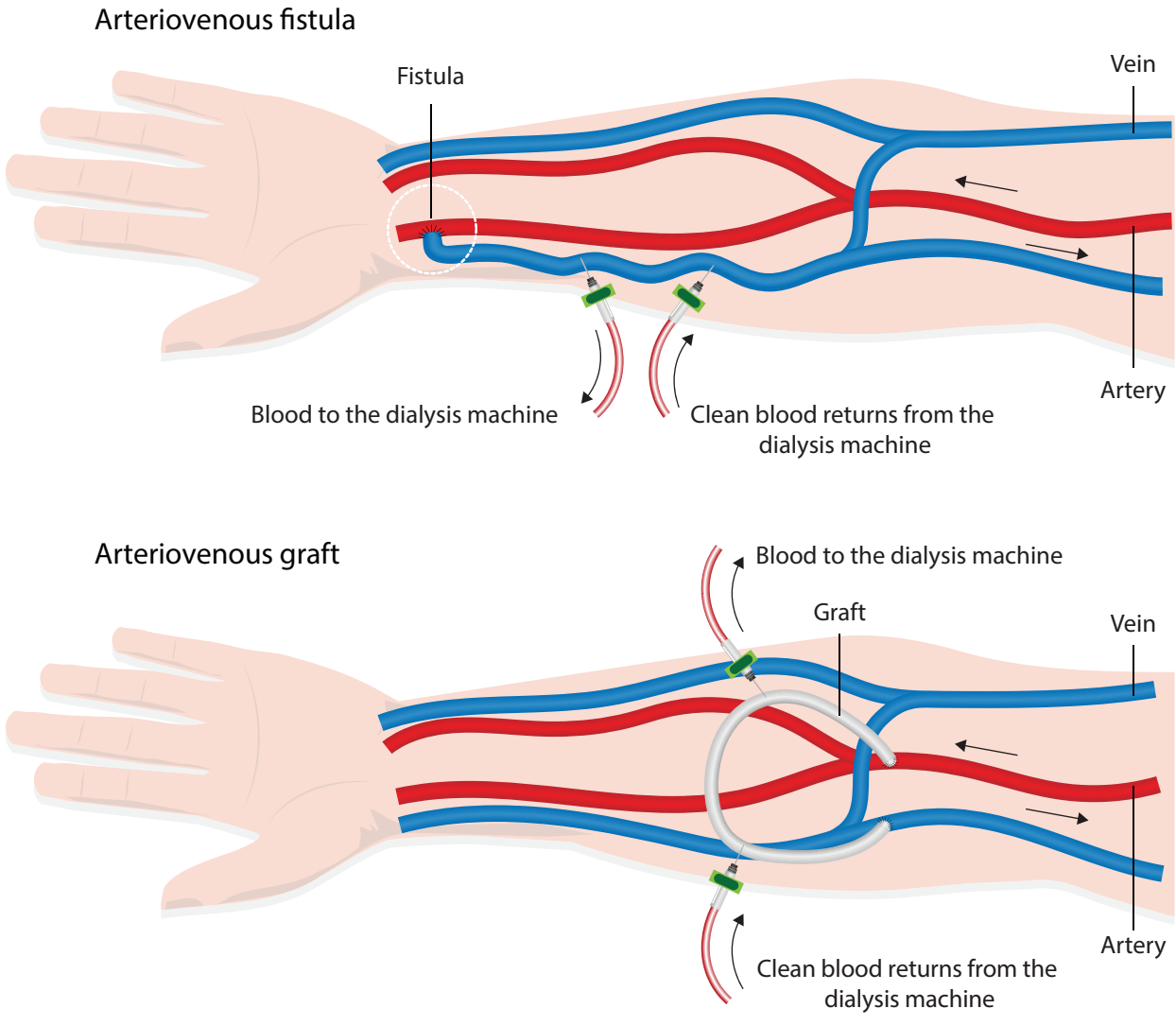
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There are 3 types of vascular access (access to veins): an arteriovenous (AV) fistula, an AV graft, or a catheter.

- A fistula is created by a surgeon connecting an **artery** to a vein with sutures or stitches to make a larger, more accessible blood vessel, usually in a patient's forearm. They are used to improve blood flow for hemodialysis.

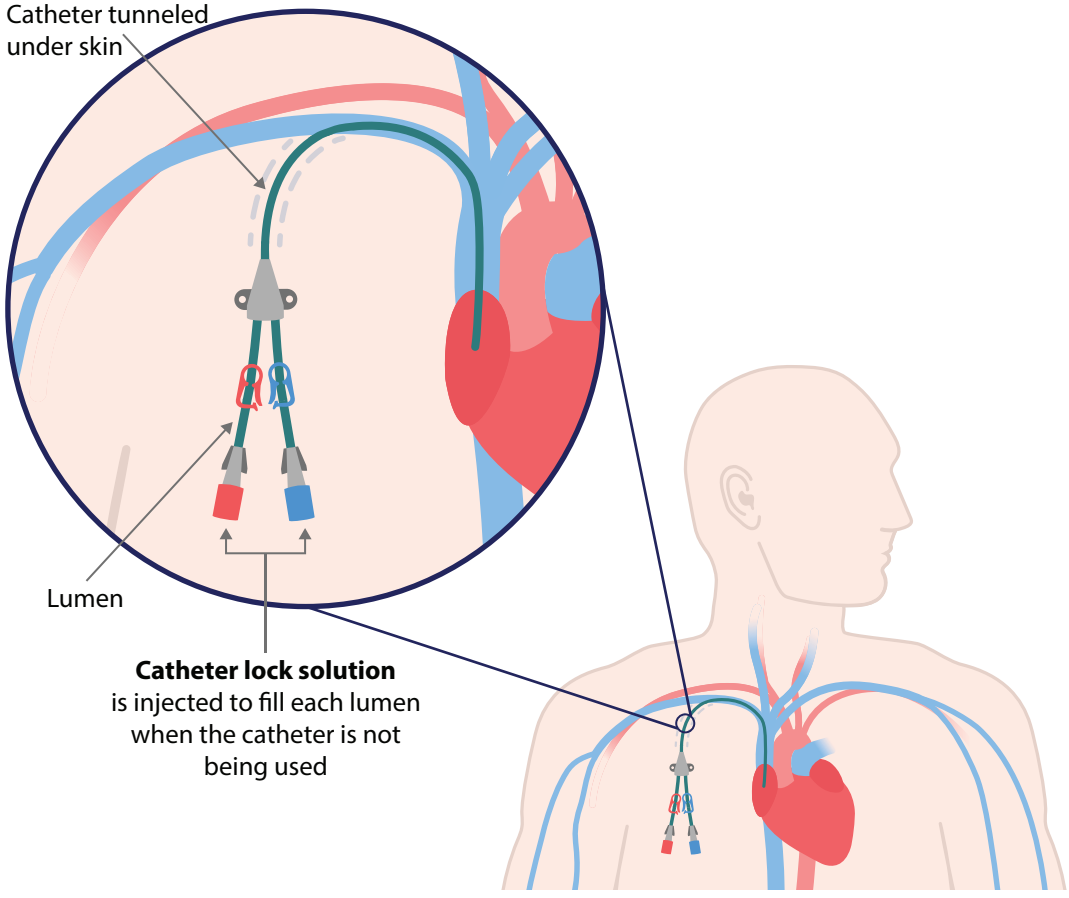
Artery: Blood vessels that carry oxygen-rich blood from the heart to the rest of the body.

- A graft uses a synthetic tube to connect an artery and vein in patients whose blood vessels are too small to form a fistula. Similar to fistulas, grafts are created by a surgeon and are used to improve blood flow for hemodialysis.
  - » Both fistulas and grafts are created by a surgeon and require time to heal or mature before a patient can begin hemodialysis treatment. Fistulas were first developed and made available in the 1960s by Drs. Appell, Cimino, and Brescia at the Bronx Veterans Affairs hospital in New York City.
  - » Fistulas have the lowest risk of infection, followed by grafts, and then CVCs, but fistulas and grafts take approximately 6 months to heal and become functional, unlike CVCs that are ready for immediate use. The benefits and risks of each option, along with the guideline recommendations, should be discussed by patients and their medical team.
- Most patients with kidney disease who are starting hemodialysis use a CVC as a vascular access to carry blood to and from the dialysis machine because of the time needed for fistulas and grafts to heal, and also in cases of late diagnosis.

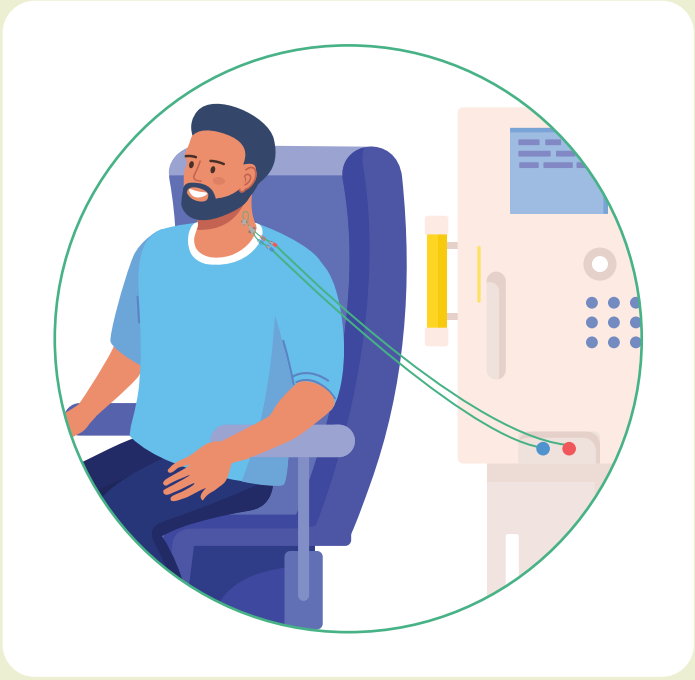


What is a central venous catheter (CVC)?

- A CVC is a long, thin, flexible tube made of medical-grade polyurethane or silicone that is inserted under the skin into a large vein in the neck, chest, or groin, and its tip is guided into a large vein near the heart or inside the heart; all central catheters are put at the juncture of superior vena cava (a large vein) and the heart to optimize blood flow.
- CVCs with 2 independent tubes, called lumens, were first proposed by Dr. Stanley Shaldon in 1961 and are still commonly used for hemodialysis today. They can also be used to administer fluids or medications and draw blood samples.
  - » One tube (the arterial lumen) carries blood from the patient with kidney disease to the dialysis machine, which acts like an artificial kidney to filter out waste and extra fluid.
  - » The clean filtered blood is returned to the patient in the other tube (the venous lumen). The tubes are capped or closed off (known as a catheter lock) in between dialysis sessions when the catheter is not being used.



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A CVC is usually meant to stay in for a short period, only until the AV fistula or AV graft is ready for use, but it can remain in place for weeks, months, or even years. For some patients, CVCs are the only way to access blood for hemodialysis due to an urgent need that cannot wait for fistulas or grafts to heal. Fistulas and grafts are generally preferred over CVCs for longer-term blood access because they provide faster blood flow to the hemodialysis machine and are less likely to result in complications, such as infection and thrombosis (the formation of blood clots).

What is a catheter-related bloodstream infection (CRBSI)?

A CRBSI is a type of **bloodstream infection** caused by microbes (germs), such as bacteria and fungi, that grow in the catheter lumen and spread to the blood.

Bloodstream infection: An infection caused by microbes (germs), such as bacteria and fungi, entering the bloodstream (for example, through a cut).

Microbes can get into the catheter by migrating from the skin of the patient through the lumens or through connection to the dialysis machine. CRBSIs are a common complication of CVC use.

CRBSIs caused by bacteria occur at a rate of 0.6 to 6.5 episodes per 1000 catheter days (a single day with a catheter equals 1 catheter day, thus, 365 catheter days equals 1 year). Patients with a CRBSI may experience symptoms such as fever (high temperature, feeling hot), sweats, chills, shakes, and feeling disoriented and not like their usual self.

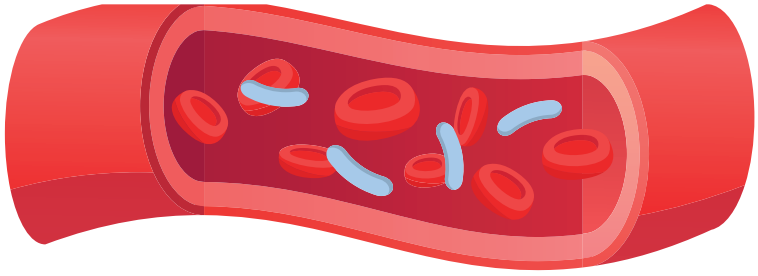
Why are CRBSIs a concern?

If not treated properly, CRBSIs can and do lead to serious and potentially life-threatening conditions, such as **septic shock** (critically low blood pressure in response to a severe infection) and/or **multiple organ system failure**, or even death. In addition to the profound impact on patients' health, CRBSIs can also result in high health care costs that impact health care systems, taxpayers, and individuals. The average hospitalization cost of a CRBSI with a hemodialysis CVC is approximately $17,000 to $32,000 (US dollars) per episode and is higher if complications occur.

Further, patients may experience prolonged hospital stays or multiple episodes, which means they will incur more frequent copays and expenses. These bloodstream infections may also cause patients to miss work and spend time away from their families and may negatively impact their mental and emotional health. If a patient shows signs and symptoms of a CRBSI, they should contact their health care providers immediately or seek urgent treatment at a hospital or urgent care center.

Septic shock/sepsis: Occurs when an infection (usually a bacterial or fungal infection) causes dangerously low blood pressure and organ failure. It is life threatening.

Multiple organ system failure: When 2 or more organ systems stop working, for example the heart and the kidneys.



CVCs, including those used **for hemodialysis,** account for **70%** of access-related **bloodstream infections**

36,000 cases of CRBSIs associated with **CVCs** occurred in the United States in 2021

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Patient perspective

I developed a CRBSI when I was 35 years old, 2 months after starting dialysis with a CVC. The first symptom I had was pain at the site of the CVC. I was admitted to the emergency room and given **antibiotics**, but I did not respond to treatment. My condition worsened and I lost consciousness. I had developed sepsis as a complication of a CRBSI, which was confirmed with **blood culture tests** that revealed the presence of bacteria in my blood. My doctors treated me with different antibiotics to help fight the infection and removed the infected catheter. I ended up spending 9 days in the hospital and spent 1.5 months on medical leave from work. The impact that the CRBSI had on my physical health was overwhelming, especially when I was advised by my physicians that due to the scar tissue from the infection, I would no longer be able to use that site for another CVC. My mental health was also impacted by the fact that I was unable to care for my 2 young girls, who had to be cared for by family members throughout my hospitalization. The CRBSI also had a considerable impact on my family's emotional well-being as they were filled with worry from having a loved one in the intensive care unit. My daughters, in particular, were fearful that their mother was not present for them as they had to be placed with family members. I, on the other hand, was in and out of consciousness and not aware of my surroundings during this time. The CRBSI also negatively impacted my work and financial well-being. During this time, I was a Senior Account Executive for a telecommunications company, and as a single parent, I depended on my income to raise my daughters. Missing more than 2 weeks of employment placed a strain on my financial stability.

Given the negative impacts that can be caused from a CRBSI, hemodialysis patients with CVCs, as well as their caregivers, should ask their doctor about how to prevent infections and be able to choose which available option is best for them.
– Celina Medina, Kidney Patient Advocate

Antibiotic: A type of antimicrobial that kills or stops the growth of bacteria.

Blood culture test: A laboratory procedure where blood samples are examined for bacteria, fungi, or viruses that may cause infections.

How can CRBSIs be prevented?

Good hand hygiene and 'scrub the hub' techniques while handling the catheter can help prevent CRBSIs. Health care providers should thoroughly wash their hands and put on new, clean gloves before accessing a CVC. The catheter hub (the end of the catheter that sits outside the body) should be scrubbed with an appropriate disinfectant before connecting the catheter to a dialysis machine. The hub should be scrubbed again after dialysis when the catheter is disconnected from the machine and before new caps are attached.

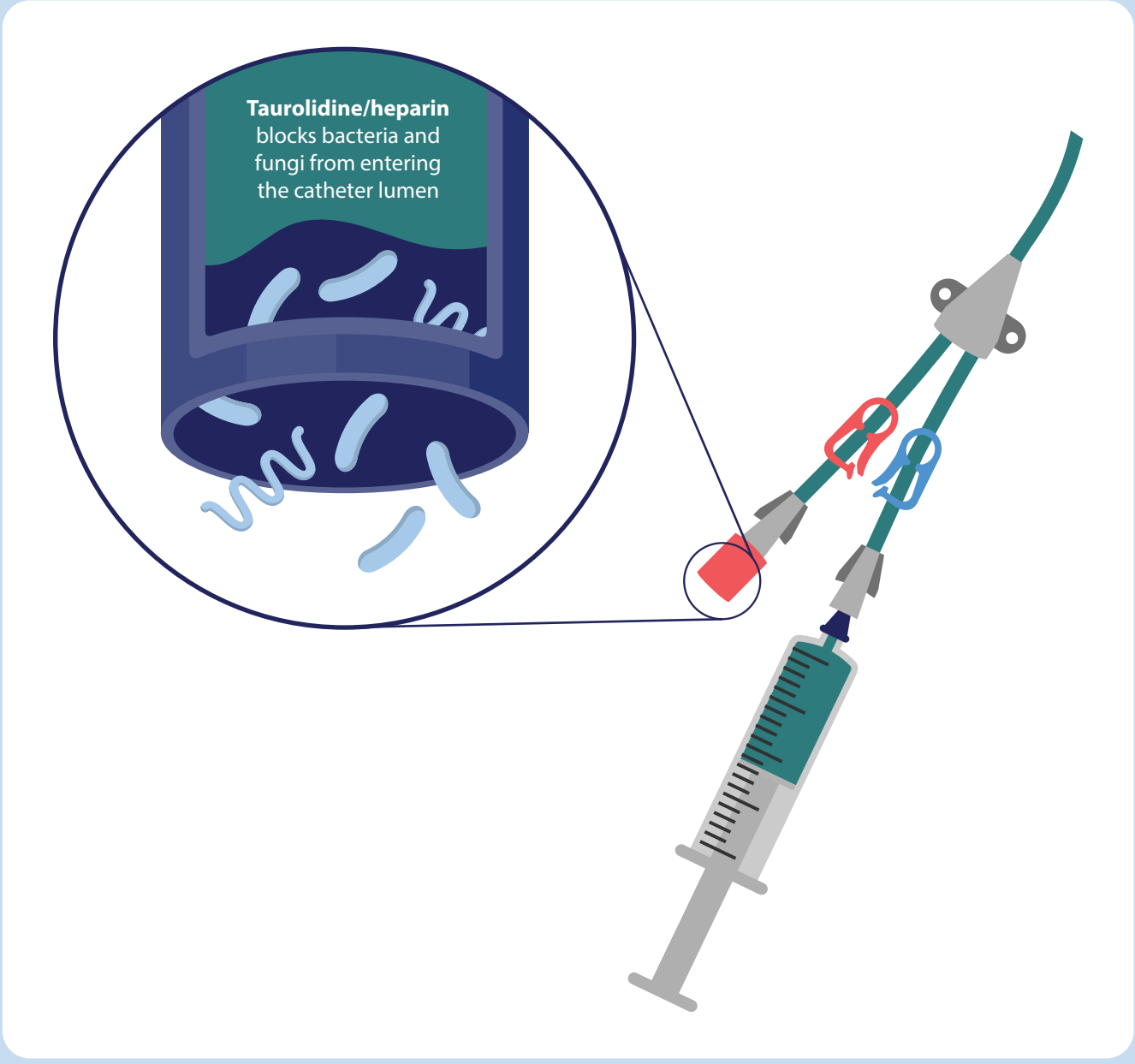
Catheter lock solutions are liquids that are put in to fill the catheter lumens or tubes after each hemodialysis session. Catheter lock solutions can be limited to a blood thinner, like heparin, to prevent blood from clotting (forming clumps) and blocking the catheter. Catheter lock solutions may also include **antimicrobial** substances that kill or prevent the growth of microbes in the catheter, which can also help prevent CRBSIs.

Antimicrobial: A substance that kills or stops the growth of microbes (germs), such as bacteria, fungi, and viruses.

What is the taurolidine/heparin catheter lock solution?

Taurolidine/heparin is a new antimicrobial catheter lock solution that contains both taurolidine and heparin. Heparin is a blood thinner that prevents blood from clotting (forming clumps) and blocking the catheter. Heparin alone is the standard catheter lock solution used in the United States, but it does not have any antimicrobial properties. Taurolidine is an antimicrobial drug that works against many types of bacteria and fungi.

The taurolidine/heparin catheter lock solution is taken out of the catheter before the start of a dialysis session and is not intended to enter the body. However, taurolidine has been shown to be safe if it leaks into the bloodstream or is accidentally flushed through the catheter instead of being removed prior to dialysis.



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What was the aim of the LOCK IT-100 study?

The LOCK IT-100 study compared the taurolidine/heparin catheter lock solution with a heparin catheter lock solution to find out which one would be more effective in preventing CRBSIs in patients receiving hemodialysis with a CVC.

Who participated in the study?

At the time the study was conducted (December 2015 to October 2018), LOCK IT-100 was the largest double-blind clinical study in the United States for people receiving hemodialysis through a CVC. Double-blind means that neither the participants nor the researchers were aware of who was receiving which catheter lock solution. The study was conducted at 150 dialysis sites located throughout the United States and enrolled patients from different ages, ethnicities, and socioeconomic backgrounds.

LOCK IT-100 study

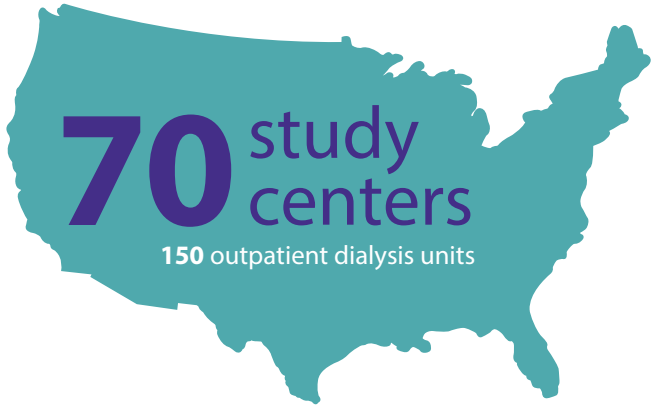
806 participants

18 years of age or older

Receiving **hemodialysis 2 or more times a week** in an outpatient center

Had **CVCs** that were placed in the body for **at least 14 days**

Had **CVCs** that were successfully used for **dialysis at least 2 times** before enrolling in the study



Centers included

Large dialysis organizations

Independent centers

US Veterans Affairs system

The LOCK IT-100 study protocol (a document describing all the procedures within the study) was approved by the appropriate institutional review board (a committee of individuals at the institution that review and approve the procedures proposed in the study). Additionally, all participants gave written informed consent to participate in the study.

What were the characteristics of the people who participated in the study?

The participants of LOCK IT-100 were representative of those receiving hemodialysis in the United States, meaning their characteristics were similar with regard to age, weight, body mass index (BMI; a measure of body fat based on comparing a person's weight and height), sex, and ethnicity. Most participants (68%) had been receiving dialysis for 1 year or less. The characteristics of participants in the taurolidine/heparin group were similar to the characteristics of participants in the heparin group.

Taurolidine/heparin group

403 participants

average **61** years old

average **30** kg/m² BMI

46% female

62% White

31% Black

4% Asian

less than 1% Other

1% American Indian or Alaska Native

2% Native Hawaiian or other Pacific Islander

44% Hispanic or Latino

9% receiving dialysis for **30 days or less**

59% receiving dialysis for **1 to 12 months**

33% receiving dialysis for **more than 12 months**

Heparin group

403 participants

average **61** years old

average **29** kg/m² BMI

38% female

65% White

28% Black

4% Asian

1% Other

less than 1% American Indian or Alaska Native

1% Native Hawaiian or other Pacific Islander

47% Hispanic or Latino

8% receiving dialysis for **30 days or less**

61% receiving dialysis for **1 to 12 months**

31% receiving dialysis for **more than 12 months**

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What happened in the study?

This was a randomized study, which means that researchers used a computer program to randomly pick which patients received the taurolidine/heparin catheter lock solution and which received only heparin as a catheter lock solution. Half of the participants received a catheter lock solution containing taurolidine/heparin, and the other half received only heparin. To ensure blinding, both solutions looked the same.

After the participant had received hemodialysis, the CVC lumens were filled with the assigned catheter lock solution; however, the solution was not intended to enter the body. The catheter lock solution was removed from the CVC before the next hemodialysis session, and a fresh catheter lock solution was filled at the end of each dialysis session.

What were the key questions answered in the study?

- How long did it take for participants in the taurolidine/heparin and heparin groups to develop a CRBSI?
- How long did it take before the CVC was removed in each group?
- How long did it take before the CVC became blocked in each group?
- What side effects were reported in each group, and how many occurred?

How did the researchers know if a CRBSI occurred?

When the study was originally designed, a CRBSI must have met the following requirements:

- To confirm that the CRBSI was the cause of an infection, the same type of microbe had to be found in a blood sample taken from:
  - » A peripheral site, such as the participant's arm, or from the dialysis bloodline
    AND
  - » The catheter hub (or dialysis bloodline if the participant was on dialysis)
- Participants must have also shown clinical signs that were suspected to have been caused by a CRBSI, including:
  - » At least 1 of the following symptoms:
    - ○ Fever (37.8°C/100°F or greater)
    - ○ Shivering/shaking, often with sweating

    OR
  - » At least 2 of the following signs:
    - ○ Fast heart rate (more than 100 beats per minute)
    - ○ Rapid breathing (more than 24 breaths per minute)
    - ○ A **systolic blood pressure** less than 90 mmHg or a decrease in systolic blood pressure of more than 30 mmHg
    - ○ Change in mental status (for example, the participant may have become confused, disoriented, or showed unusual behavior)

Systolic blood pressure: It is the top number in a blood pressure reading that represents the pressure in arteries when the heart pumps blood out into the circulation with each heart beat due to the force exerted against the artery walls.

CRBSIs were assessed by an independent Clinical Adjudication Committee, composed of key medical experts.

As the study progressed, investigators found that most patients showed signs of a CRBSI after they had left the dialysis center.

When these patients went to an emergency facility or hospital, typically only 1 blood sample was taken (instead of the 2 samples required by the study). Because of this, the study was changed based on guidance from the Centers for Disease Control and Prevention (CDC) after discussions with the US Food and Drug Administration (FDA), which is the US regulatory body for medical treatments, to allow all the required information (including blood test results) to be obtained from medical records during the time when the patient was showing signs of infection.

The Clinical Adjudication Committee reviewed the information and could ask for more details to make sure no other sources of infection were present.

What were the overall results of the LOCK IT-100 study?

About halfway through the study, once the first 28 CRBSI cases occurred, study data collected to that point were analyzed (**planned interim analysis**) to monitor study progress and determine if any changes to the study conduct were needed. CRBSIs occurred in 6 (2%) participants in the taurolidine/heparin group compared with 22 (7%) participants in the heparin group. Use of the taurolidine/heparin catheter lock solution was shown to delay the time it took for participants to develop a CRBSI and reduced the risk of CRBSIs by 72% compared with the use of heparin alone. These results were so highly in favor of using taurolidine/heparin as a catheter lock solution choice that the **Data and Safety Monitoring Board** recommended that the study stop early. Stopping early required discussions with and approval from the FDA.

Until approval was received, data collection continued for participants who were already enrolled and recruitment of new participants continued. After the FDA agreed that the study could end early, no new participants were recruited; however, follow-up and data collection continued for all participants who had been enrolled. Thus, there were additional data for the **final analysis** even though profound effects of the taurolidine/heparin lock were already observed by the interim analysis.

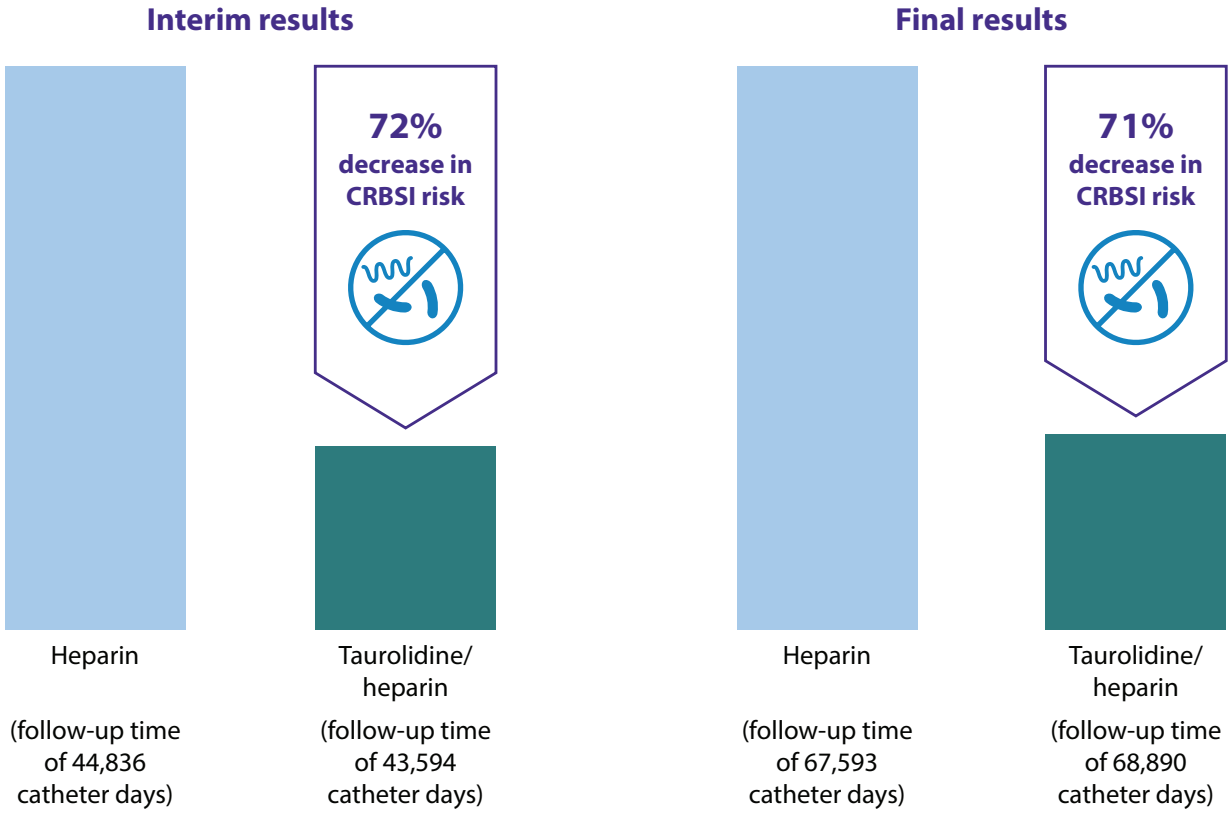
Planned interim analysis: A pre-defined time point before the end of the study where data are reviewed to evaluate the efficacy and/or safety of the study treatment. This can potentially allow for stopping the study early or modifying the study procedures depending on any benefits or harms seen at this early point in the study.

Data and Safety Monitoring Board: A group of experts in the condition being studied and statisticians who closely watch over a clinical trial to make sure procedures are conducted safely and monitor study progress.

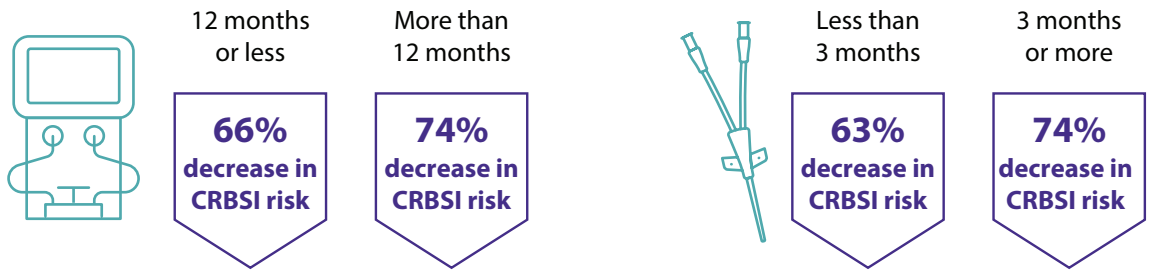
Final analysis: An evaluation of all the data collected over the entire study.

In the final analysis, CRBSIs occurred in 9 (2%) participants in the taurolidine/heparin group compared with 32 (8%) participants in the heparin group. Taurolidine/heparin, confirmed by statistical significance (a method to determine that a study result is likely due to the intervention being studied and did not happen by chance), delayed the time it took for participants to develop a CRBSI and reduced the risk of developing a CRBSI by 71% compared with heparin alone. The results similarly favored taurolidine/heparin regardless of the amount of time the patient had been receiving dialysis or the age of their catheter.

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CRBSI risk decreased with **taurolidine/heparin** compared with **heparin** alone in participants from the full study population and in different groups of participants based on the time since their first dialysis and the age of their catheter



Did the catheter lock solutions that were used in the study impact the time until the catheter was removed?

There was no difference between the study groups in the amount of time to catheter removal for any reason. For participants in the taurolidine/heparin group, 236 (59%) had their catheter removed. For participants in the heparin group, 225 (57%) had their catheter removed.

During the study, catheters were removed for a variety of reasons, including:



The catheter was no longer needed for hemodialysis because the participant's kidney function improved, they received a kidney transplant, or their fistula matured



The catheter did not work properly



The participant experienced a CRBSI

Did the catheter lock solutions that were used in the study impact the time until the catheter became blocked?

The catheter became blocked with blood clots in 63 (16%) participants in the taurolidine/heparin group and 48 (12%) participants in the heparin group. There was no statistically significant difference between the study groups in the amount of time to catheter blockage, meaning that this outcome is likely real and did not happen by chance.

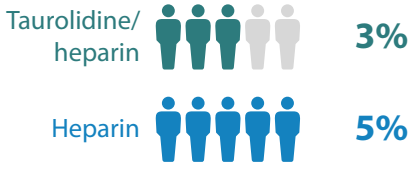
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What were the most common side effects?

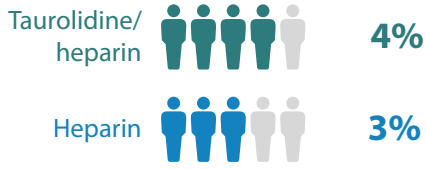
The types of side effects reported in LOCK IT-100 were expected based on side effects that have been reported in other dialysis clinical studies. There were no significant differences in safety between the 2 study groups. An equal percentage (79%) of participants in the taurolidine/heparin group and heparin group experienced a side effect. Most side effects were classified as mild to moderate. There were no serious side effects that were considered to be caused by using the taurolidine/heparin catheter lock solution, although study doctors noted that 1 serious side effect (a catheter that failed to work properly) was possibly related to using the taurolidine/heparin catheter lock solution.

Serious side effects that occurred in 2% or more of participants in either the taurolidine/heparin group or the heparin group:

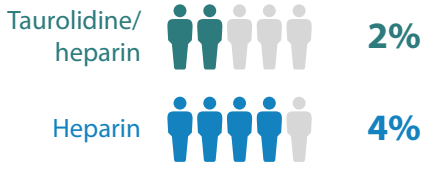
Pneumonia
(a type of lung infection)



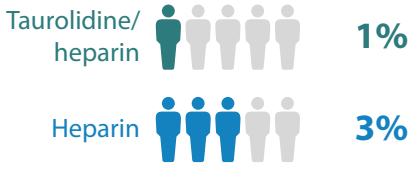
Fluid overload
(too much liquid in the body)



Sepsis
(extreme response to an infection)



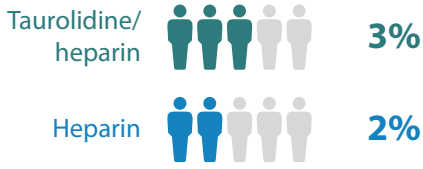
Acute myocardial infarction
(heart attack)



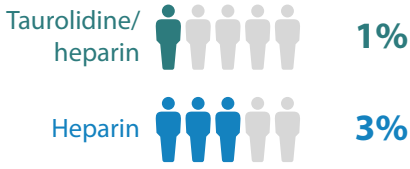
Congestive heart failure
(long-term condition where the heart is unable to sufficiently pump blood around the body)



Hyperkalemia
(high potassium)



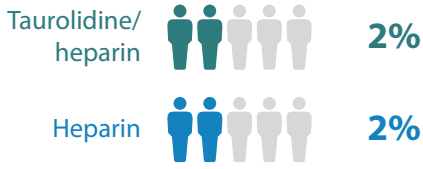
Hypertension
(high blood pressure)



Respiratory failure
(breathing system failure)



Device (catheter)-related infection



Frequently asked questions

Q. What should I do if I suspect a CRBSI?
A. If you experience signs and symptoms of a CRBSI, such as fever, sweats, chills, shaking, or confusion, you should seek urgent treatment at a hospital or urgent care center.

Q. How can I talk to my health care provider about using taurolidine/heparin?
A. If you are interested in using taurolidine/heparin, ask your health care provider if it is available at your center and if it is appropriate for you.

Q. Are there any long-term effects of using taurolidine/heparin?
A. In the LOCK IT-100 study, people used taurolidine/heparin for an average of 173 days (ranging from 4 to 863 days). The side effects that occurred in the taurolidine/heparin group were similar to those that occurred in the heparin group. Most side effects were classified as mild or moderate. Taurolidine/heparin is only to be used as a catheter lock solution and is not meant to enter the body.

Q. What is the difference between taurolidine/heparin and antibiotics such as vancomycin and gentamicin?
A. The taurolidine/heparin catheter lock solution contains the antimicrobial taurolidine. Antimicrobial substances kill or stop the growth of different kinds of microbes (germs), such as bacteria, fungi, and viruses. Vancomycin and gentamicin are antibiotics. Antibiotic substances kill or stop the growth of bacteria but are not effective against other kinds of microbes like fungi.

Q. Has antimicrobial resistance been observed with taurolidine/heparin in humans?
A. Antimicrobial resistance occurs when microbes change or adapt so that they no longer respond to antimicrobial drugs. To date, there have been no cases of antimicrobial resistance reported with taurolidine/heparin.

Q. Where does taurolidine come from?
A. Taurolidine is made from taurine, an amino acid (a type of chemical that is the building block of protein) that occurs naturally in the body.

Practical tips for patients with kidney disease on dialysis and caregivers

It is important to follow your health care provider's instructions on how to care for your CVC. Be sure to practice good hand hygiene before and after touching the CVC. This includes washing your hands with soap and water and scrubbing for at least 20 seconds. If you do not have access to soap and water, use a hand sanitizer that contains at least 60% alcohol. Keep the dressing clean and dry. Do not let your CVC get wet when you shower. Do not take baths, use a hot tub, or go swimming. Contact your health care provider right away if you notice cracks, leaks, or other damage to your CVC.

Patients with kidney disease on dialysis and caregivers should always be looking out for signs and symptoms of an infection. These include pain, redness, or swelling around the catheter access site. The patient may also experience fever, chills, shaking, sweats, rapid heart rate or fast breathing, tiredness, confusion, or trouble concentrating. If any of these signs or symptoms occur, immediately alert a health care provider, such as a physician or nurse, so the patient can be carefully assessed for a CRBSI. Your doctor will order blood tests to screen for an infection and, if necessary, order treatment. The goal of using the taurolidine/heparin catheter lock solution is to reduce the incidence of CRBSIs, but patients and caregivers must always be aware of the signs and symptoms in case they occur.

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Summary of key points

- This is a summary of an article originally published in the *Clinical Journal of the American Society of Nephrology* about the LOCK IT-100 study.
- The LOCK IT-100 study looked to see if using the taurolidine/heparin catheter lock solution can reduce the risk of CRBSIs compared with using a catheter lock solution containing only heparin in patients with kidney disease receiving hemodialysis through a CVC.
- The taurolidine/heparin catheter lock solution contains taurolidine, an antimicrobial agent, and heparin, a blood thinner.
- Taurolidine/heparin significantly reduced the risk of CRBSIs by 71% when compared with heparin alone.
- Taurolidine/heparin was shown to be safe and effective in this large study that enrolled more than 800 patients.

Where can readers find more information on this study?

The original article of this study 'Taurolidine/Heparin Lock Solution and Catheter-Related Bloodstream Infection in Hemodialysis: A Randomized, Double-Blind, Active-Control, Phase 3 Study.' Agarwal, Anil K *et al*. *Clinical Journal of the American Society of Nephrology,* 2023, Volume 18, Issue 11, 1446-1455, can be read at: https://journals.lww.com/cjasn/fulltext/2023/11000/taurolidine_heparin_lock_solution_and.11.aspx.

You can read more about the LOCK IT-100 study on the ClinicalTrials.gov website (http://www.clinicaltrials.gov) by entering the study identification number NCT02651428 in the 'Other terms' search field.

This study was started in December 2015 and was completed in October 2018. There are no plans for further analysis.

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Disclosure statement

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ORCID details

Antony Pfaffle 0000-0002-4144-253X
Paul T. Conway 0000-0002-3344-6936
Edward V. Hickey III 0000-0003-4725-2179

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