



## HEMODIALYSIS TUNNELED CATHETERS LOCK WITH TAUROLOCK™ VERSUS A COMBINATION OF GENTAMYCINE AND HEPARINE

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### ABSTRACT

**Purpose:** Catheter-related infections and thrombosis are the most common complications associated with the use of tunneled hemodialysis catheters.

The aim of our study was to determine the incidence of these complications in patients who underwent “locking” of their tunneled catheters and compare the cost of different options with their effect.

**Materials and Methods:** The study was conducted in the period 01.10.2021 - 31.03.2022. Twenty-three men and twenty-two women with a mean age of 60.82 (+/-13.629) years were randomly divided into three groups of 15 (fifteen) people each. Group A – catheter locking with TauroLock™ only, group B – with gentamicin and heparin; group C – with TauroLock™ for three months, then with heparin and gentamicin for the next three months.

**Results:** The median duration for tunneled catheters was 8,105 catheter-days. One complication was reported in each of the three groups. Reported costs for patients treated with TauroLock™ were calculated at 3 EUR/each dialysis session and for patients treated with gentamicin and heparin – 0.88 EUR/dialysis session.

**Conclusion:** The data from our study unequivocally support the thesis that locking the catheter with a TauroLock™ is comparable to the effect of the solution containing an antibiotic and anticoagulant.

**Keywords:** hemodialysis, catheter-related infections and dysfunction, catheter lock solutions, TauroLock™, management of tunneled catheter,

### INTRODUCTION

Infectious complications of central venous catheters (CVC) are the most frequently cited late complications. They are associated with the essential risk to patients' lives. Up to 250,000 cases of catheter-related infections are established annually in the USA, which are the cause of death for 25% of those patients [1, 2, 3].

The risk of infections in patients undergoing hemodialysis depends on catheter type, place of insertion, the time of its exploitation and the established aseptic rules in the relevant dialysis unit. The frequency of bacteremia is estimated at 1.8 to 6.2/1000 catheter-days (CD) - for CVC; metastatic infectious complications such as endocarditis, osteomyelitis, infectious arthritis, catheter sepsis has a frequency of 1.1/1000 CD [4, 5]. The cost of treatment can reach 60,000 US dollars [6]. A wide variety of antibiotic and antiseptic solutions have been used to flush or lock the catheter lumen to prevent catheter-related infections. Catheter locking is a methodology where an antimicrobial solution is used to fill the lumen of the catheter between dialysis sessions. Antibiotics with different concentrations - alone or in combination for locking the central venous catheters include vancomycin, gentamicin, cefazoline etc., while antiseptics are mainly alcohol, taurolidine and trisodium citrate [2].

Catheter dysfunction is a very common problem associated with chronic catheter use. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) has published guidelines that define “dysfunction”. According to these guidelines, catheter-associated thrombosis is the main cause of catheter dysfunction and is the cause of the loss of vascular access in 30-40% of patients and in 17 to 33%, it is the cause of premature removal of the catheter [7, 8].

The aim of our study was to determine the incidence of these complications in patients who underwent “locking” of their tunneled catheters and compare the cost of different options with their effect.

### MATERIALS AND METHODS

The patients included in the study signed an Informed Consent (No.654/29.06.2021) approved by the Research Ethics Committee at MU-Pleven. The study was conducted in the period 01.10.2021 - 31.03.2022, a total

of six months. The study included 23 men and 22 women with an average age of 60.82 (+/-13,629) years, and the age difference between the three groups can be considered insignificant ( $p=0.046$ ).

The tunneled catheters used in the patients were: ARROW CANNON® II PLUS (Arrow International, Inc. Reading, PA19605 USA) split (polyurethane), 15 Fr, 28 and 32 cm (23 and 27cm – from tip to cuff), split system; HEMO-FLOW® (Medcomp, Harleysville, PA 19438 USA) single body (SB), 14.5 Fr, 24 and 28 cm (polyurethane); PALINDROME™ symmetric tip Dual lumen catheter, (Covidien, Mansfield, MA 02048 USA), palindromic type, 23 and 28 cm (carbothane).

Chemoculture media BD BACTECR Plus Aerobic/F (Bacton, Dickinson and Company, Sparks, MD 21152) were used. Precise identification and antibiotic sensitivity were performed with a VITEK 2 apparatus (Vio Merieux, France).

All patients had tunneled catheters placed >3 months ago (mean duration was 714 +/- 247 catheter-days) as the only vascular access for hemodialysis treatment. After a clinical examination and a negative result of two blood cultures, the patients were randomly divided into three groups of 15 (fifteen) people each, a total of 45 (forty-five) participants: group A – locking the catheter only with TauroLock™ (Tauropharm, Waldbüttelbrunn, Germany), group B – locking with gentamicin (10 mg/ml) and heparin (1250 IU/ml) and group C – locking with TauroLock™ for three months, then – with heparin and gentamicin for the next three months of the study. Patients were monitored for the major complications of catheter-related infection (CRI) and catheter-related thrombosis (CRT).

All data were statistically processed with Statgraphics 19.

#### Main points:

- Our study has an original design.
- The mean catheters duration before the study was more than 90 days.
- We use a combination of gentamicin and heparin vs TauroLock™.
- Observation time was sufficient.

#### RESULTS

Thirty-nine patients completed the study, six people died due to COVID-19 infection, and the mean age of those who died was significantly higher (67.3 vs 59.8 age) than that of those who completed the study ( $p=0.036$ ). The median length of stay for tunneled catheters was 8,105 catheter-days. One complication was reported in each of the three groups: group A – one case of catheter related infections-CRIs (Figure 1), which was calculated to be 0.4/1000 CD (by this group). Groups B and C – one case of CRT each. No cases of catheter-associated bloodstream infection requiring prolonged treatment and catheter thrombosis requiring replacement of the tunneled catheter were reported.

Reported costs for patients treated with TauroLock™ were calculated at  $\hat{3}$ /per dialysis session and for patients treated with gentamicin and heparin –  $\hat{0.88}$ /dialysis session.

**Fig. 1.** Catheter-associated exit site and subcutaneous tunnel infection (our case).



The case of catheter-related infection showed no growth from blood culture, *Staphylococcus epidermidis* was isolated from local secretion, the tunneled catheter was replaced over a metal guidewire with the creation of a new tunnel, and parenteral treatment with levofloxacin - 500 mg/daily, for 10 days was carried out. In the two cases with catheter-related thrombosis, urokinase was administered - 25,000 IU, with good effect.

#### DISCUSSION

The use of central venous catheters has continued to increase in recent decades, and according to data from the Centers for Medicare and Medicaid Services (CMS), their share is estimated at about 29% in the first six months of hemodialysis treatment, they are more than 69% of vascular access, and at the end of the first year – over 41% of patients still have dialysis catheters [9]. Their use is associated with frequent complications such as catheter-related thrombosis and infections, which generate huge costs for the healthcare system, worsen the quality of life of patients and are often the cause of their death [4, 5, 6]. The present rules of good clinical practice recommend the use of antibacterial agents and anticoagulants for the prevention of these complications, especially in patients with no alternative for their vascular access or frequent catheter infections –  $>3.5/1000$  CD [10]. These substances are used to lock the catheter at the end of dialysis sessions.

TauroLock™ is a product of the company Tauro Pharm (GmbH August-Bebel-Str. 51 97297 Waldbüttelbrunn, Germany) and contains 1.35% taurolidine with antibacterial and antifungal action and 4% sodium citrate as an anticoagulant [11]. Compared with solutions for filling central venous catheters containing heparin, it shows

a significantly lower number of cases of infectious and thrombotic complications [12, 13, 14, 15]. It is a non-toxic agent that reduces bacterial biofilm formation and does not induce bacterial resistance [12]. As usual, there are also authors who disagree with the presented conclusions for various reasons [16]. In most of the studies cited, taurolidine-citrate was primarily compared with plain heparin [13, 14], with some designs using intermittent urokinase. In addition, studies are often done for periods of less than 6 months and in patients with newly inserted tunneled catheters, which rarely develop serious complications until the 90th day after implantation [12].

The filling of central venous catheters with solutions containing different antibiotics with/without the addition of an anticoagulant (most often heparin) is discussed in the world literature [5]. In the last decade, the use of gentamycin +/- cefazolin +/- heparine was most frequently mentioned [17, 18]. Intraluminal administration of the antibiotic and its withdrawal with a syringe before the next dialysis session is associated with a small risk of the drug entering the patient's circulation and related complications [19, 20]. There are studies that have been randomized and directly compared the effect of TauroLock™ with that of a mixture of antibiotic and anticoagulant [17, 18, 19, 21].

In patients with tunneled catheters and a high risk for infectious complications (>3.5/1000 CD), the prophylactic

use of a mixture of antibiotic and anticoagulant is recommended [10, 22].

Our study differs from most similar studies because it was conducted in patients with a long-standing tunneled catheter and has a design that we did not find in international databases. Its duration of six months is an optimal duration, and the number of patients is sufficiently large compared to similar studies.

## CONCLUSION

The data from our study unequivocally support the thesis that locking the catheter with a solution containing TauroLock™ is comparable to the effect of locking the catheter with a solution containing an antibiotic and anticoagulant. In the short term, the difference in the price of medicines is significant, but it does not exceed the potential losses of public funds in the medium and long term. We recommend the use of a similar prophylactic regimen in all patients with tunneled catheters as the only possible vascular access for hemodialysis or with an expected duration of use greater than ninety days.

## ACKNOWLEDGMENTS

The present study was funded by funds provided by the Medical University-Pleven, for which we express our gratitude.

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*Please cite this article as:* Borisov BK, Vasileva VT. Hemodialysis tunneled catheters lock with TauroLock™ versus a combination of gentamycin and heparine. *J of IMAB*. 2023 Jul-Sep;29(3):5045-5048. [Crossref - <https://doi.org/10.5272/jimab.2023293.5045>]

Received: 12/02/2023; Published online: 28/07/2023

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