Introduction

Nowadays, medical sciences and technology are rapidly progressing. The life expectancy of survivors is increasing. One of the survivors is spinal cord injury (SCI) patients who have alteration of urological function and require the use of bladder management for urinary drainage such as indwelling catheterization, intermittent catheterization, and urinary condom.\(^1\) Urinary tract infection (UTI) is the most common sequela in SCI patients.\(^2\) They frequently take various types of antibiotic medications by primary care physicians’ order. In spite of advances in medical treatment, SCI patients still have UTI.\(^3\) Risk factors of UTI in SCI patients are vesicoureteral reflux, high detrusor pressure, stone in urinary system, poor perineum hygiene care, inadequate fluid intake, and improper bladder management.\(^4\)

The diagnosis UTI in the general population is based on urinary symptoms, urine analysis, and urine culture.\(^5\) This approach cannot be applied to individuals with SCI because of their impaired neurological function and urinary system.\(^6\) However, a standard test for UTI diagnosis in SCI patients is cited from the National Institute on Disability and Rehabilitation Research criteria (NIDRR).\(^8\) The NIDRR consensus statement sets the

Abstract

Aims: The aim of this is to evaluate the reliability of the urine dipstick test by patients’ self-assessment for urinary tract infection (UTI) screening and to determine the validity of urine dipstick test. Settings: Rehabilitation Department, Srinagarind Hospital, Thailand. Study Design: A diagnostic study. Subjects and Methods: This study compared the urine dipstick test (index test) with the National Institute on Disability and Rehabilitation Research (NIDRR) criteria (gold standard test) in spinal cord injury (SCI) patients. The urine dipstick test informed positive and negative results. Besides the NIDRR criteria classified as UTI and no UTI. The interrater reliability was measured in the sense of Kappa whereas the validity of urine dipstick test was reported in terms of sensitivity, specificity, positive likelihood ratio (LR (+LR)), negative LR (-LR), positive predictive value (PPV), and negative predictive value (NPV). Results: Out of the 56 participants, the kappa of urine dipstick test for leukocyte esterase, nitrite, and combined leukocyte esterase and nitrite were 0.09, 0.21, and 0.52, respectively. The nitrite urine dipstick test showed the highest sensitivity (90%). The combined leukocyte esterase and nitrite urine dipstick test gave the highest specificity (87%), PPV (60%), NPV (93%), and +LR (5.63). Conclusions: The interrater reliability of combined leukocyte esterase and nitrite urine dipstick test was moderate agreement. The combined leukocyte esterase and nitrite urine dipstick test showed high level of both sensitivity and specificity. The combined leukocyte esterase and nitrite urine dipstick test should be promoted for patients’ self-assessment for UTI screening in SCI patients.

Keywords: Spinal cord injury, urinary tract infection, urine dipstick test

The reliability and validity of using the urine dipstick test by patient self-assessment for urinary tract infection screening in spinal cord injury patients

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Introduction

Nowadays, medical sciences and technology are rapidly progressing. The life expectancy of survivors is increase. One of the survivors is spinal cord injury (SCI) patients who have alteration of urological function and require the use of bladder management for urinary drainage such as indwelling catheterization, intermittent catheterization, and urinary condom.\(^1\) Urinary tract infection (UTI) is the most common sequela in SCI patients.\(^2\) They frequently take various type of antibiotic medications by primary care physicians’ order. In spite of advances in medical treatment, SCI patients still have UTI.\(^3\) Risk factors of UTI in SCI patients are vesicoureteral reflux, high detrusor pressure, stone in urinary system, poor perineum hygiene care, inadequate fluid intake, and improper bladder management.\(^4\)

The diagnosis UTI in the general population is based on urinary symptoms, urine analysis, and urine culture.\(^5\) This approach cannot be applied to individuals with SCI because of their impaired neurological function and urinary system.\(^6\) However, a standard test for UTI diagnosis in SCI patients is cited from the National Institute on Disability and Rehabilitation Research criteria (NIDRR).\(^8\) The NIDRR consensus statement sets the
criteria for diagnosis UTI in person with SCI using significant bacteriuria (intermittent catheterization: $U/C > 10^2$ CFU/mL; urinary condom: $U/C > 10^4$ CFU/mL; indwelling catheterization: $U/C = \text{any detectable concentration}$) plus the presence of at least 1 sign or symptom of UTI (leukocytes in the urine, cloudy urine with increased odor, increased spasticity, lethargy, fever, urinary incontinence, autonomic dysreflexia, malaise, sense of unease, discomfort, or pain during urination). This criterion is involved the urine culture result which needs an incubation period of 24 h or more. Some primary care physicians make a clinical decision to treat antibiotic treatment while impending urine culture result. This condition may lead to overtreatment of antibiotic medications and further contribute to higher antibiotic resistance rates. Moreover, urine culture laboratory unit is not available at some public health-care centers or primary care hospitals. Lack of this result is one of an obstacle to primary care physicians. Therefore, NIDRR criteria cannot be applicable in those places.

Urine dipstick test which includes leukocyte esterase and nitrite is the one option for UTI screening. When the reagent on the urine dipstick detects positive nitrite, it may be caused by bacteria reducing nitrates to nitrites, which would be indicated bacteriuria. Besides reagent detection of positive leukocytes esterase can be related to pyuria. The urine dipstick test can be used for UTI screening and reduces the number of negative urine samples sent for urine culture. Moreover, primary care physicians can advise the SCI patients to self-screen UTI by the urine dipstick test because it is easy to use and inexpensive.

In recent time, there has been increased studies of how to evaluate the usefulness of urine dipstick in SCI patients. However, all of those studies compared the urine dipstick test with only urine culture or urine analysis which were not the standard criteria for UTI diagnosis in SCI patients. An only one previous study which was compared the urine dipstick test with the NIDRR criteria reported that the combined nitrite and leukocyte esterase showed the highest sensitivity (93%), positive predictive value (PPV) (79%), negative predictive value (NPV) (85%), and positive likelihood ratio (+LR) (2.39), respectively. Nevertheless, no previous studies were compared the urine dipstick test by patient assessment with the NIDRR criteria, and no previous studies reported interrater reliability of urine dipstick test between patients and laboratory results.

This study aimed to evaluate the reliability of the urine dipstick test by SCI patient self-assessment for UTI screening and to determine the validity of the urine dipstick test for UTI screening compared with the NIDRR.

**Subjects and Methods**

**Participants**

SCI patients with neurogenic bladder attended the Rehabilitation Department, Srinagarind hospital during July 2014 to July 2015. Inclusion criteria were age more than 18-year-old, history of neurogenic bladder more than 6 months and give written informed consent. Exclusion criteria were pregnancy, impaired vision, and defective communication. This study was approved by the Khon Kaen University Ethics Committee in Human Research (HE571507) and was supported by the Faculty of Medicine Research Fund, Khon Kaen University (IN58252).

**Methodology**

The participants were assessed by questionnaire, NIDRR criteria, and urine dipstick test. The method was shown as STARD flow diagram [Figure 1]. The questionnaire was informed about age, sex, neurological level, the American Spinal Injury Association (ASIA) classification, duration of injury, type of bladder management, and the presence of vesicoureteral reflux and hydronephrosis. NIDRR criteria which were a gold standard

![Figure 1: STARD flow diagram](image-url)
test was evaluated by urine culture and the presence of at least 1 sign or symptom of UTI. The urine dipstick test which was AUTION sticks 10 EA (ARKRAY incorporation, Japan) was an index test. Urine specimens from the participants were divided into two parts. First, was sent to a laboratory unit for urine analysis and urine culture and the remainder was examined by the urine dipstick test. The urine reagent pad was dipped into urine for 2 s by a professional nurse and was interpreted the colorations after dipping 2 min by the participants. Urine dipstick test was reported leukocyte esterase and nitrite levels as positive or negative.

**Statistical analysis**

Data from all participants will be analyzed according to data being available. No imputation will be implemented to missing data. All statistical tests will be two-sided with a significant level of 0.05. All statistical analysis will be implemented by using Stata 12 (StataCorp, College Station, TX, USA). All baseline characteristics were summarized in number percentage unless specified of age and duration of injury in mean and standard deviation. The interrater reliability of the urine dipstick between participants self-assessment and laboratory unit were measured in the sense of kappa whereas the validity of participants self-assessment urine dipstick test compared to NIDRR was reported in terms of sensitivity, specificity, positive +LR, negative LR (~LR), PPV, and NPV. All of validity value and its 95% confidence interval were demonstrated.

**Results**

The number of participants was 56 which male sex was 45 (80.36%). The average age was 45.01-year-old. Duration of SCI was 5.5 years. Most of the neurological level was paraplegia (73.21%). Most of the participants were classified in ASIA A classification (41.07%). Indwelling catheterization was the most type of bladder management (58.93%). Ten participants had history of vesicoureteral reflux whereas one participant had history of hydronephrosis [Table 1].

The interrater reliability (kappa)\textsuperscript{[13]} of urine dipstick test for leukocyte esterase, nitrite, and combined leukocyte esterase and nitrite were 0.09 (slight agreement), 0.21 (fair agreement), and 0.52 (moderate agreement), respectively. However, the statistical significant was detected in combined leukocyte esterase and nitrite (\(P < 0.05\)) [Table 2].

According to the validity of urine dipstick test, the urine dipstick test of combined leukocyte esterase and nitrite showed highest specificity (87%), PPV (60%), NPV (93%), +LR (5.63), respectively. The highest sensitivity was the urine dipstick test of nitrite (90%). The lowest-LR (0.21) was the urine dipstick test of nitrite [Table 3].

**Discussion**

The interrater reliability of the urine dipstick between patient's self-assessment and laboratory unit result in this study showed that the kappa of combined leukocyte esterase and nitrite urine dipstick test were lower agreement level than the previous study\textsuperscript{[16]} which reported the result of the urine dipstick test by professional nurses.

The validity of the urine dipstick test for UTI was compared with NIDRR. In this study, the sensitivity, specificity, and NPV of combined leukocyte esterase and nitrite urine dipstick test were similar as the former studies\textsuperscript{[10,14]} \*The specificity of nitrite test is trustworthy to rule out UTI in SCI patients like the previous study\textsuperscript{[17]} The specificity of leukocyte esterase urine dipstick test is reliable to diagnose UTI in SCI patients unlike the finding of the previous study\textsuperscript{[18]} Concerning PPV, the combined leukocyte esterase and nitrite urine dipstick test was similar as the former studies\textsuperscript{[10,14]} Regarding to NPV, the combined leukocyte esterase and nitrite urine dipstick test was high that was accorded with some prior studies\textsuperscript{[1,14]}. In addition, +LR of the combined leukocyte esterase and nitrite urine dipstick test was high which

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### Table 1: Baseline characteristics

| Data                              | n (%)          |
|-----------------------------------|----------------|
| Age (mean±SD)                     | 45.01±14.54    |
| Sex                               |                |
| Male                              | 45 (80.36)     |
| Neurological level                |                |
| Quadriplegia                      | 15 (26.79)     |
| Paraplegia                        | 41 (73.21)     |
| ASIA classification               |                |
| A                                 | 23 (41.07)     |
| B                                 | 9 (16.07)      |
| C                                 | 8 (14.29)      |
| D                                 | 14 (25.00)     |
| E                                 | 2 (3.57)       |
| Duration of injury (years), mean±SD | 5.50±6.52    |
| Type of bladder management        |                |
| Urinary condom                    | 6 (10.71)      |
| Intermittent catheterization      | 17 (30.36)     |
| Indwelling catheterization        | 33 (58.93)     |
| History of vesicoureteral reflux  | 10 (17.86)     |
| History of hydronephrosis         | 1 (1.79)       |

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### Table 2: The interrater reliability of urine dipstick test by self-patients assessment

| Urine dipstick | Lab | Positive | Negative | \(\kappa\) | \(P\) |
|----------------|-----|----------|----------|------------|-------|
| Leukocyte esterase |     | Positive | 9        | 0          | 0.099 slight agreement | 0.087 |
| Nitrite |     | Negative | 35       | 12         |                   |       |
| Nitrite |     | Positive | 22       | 16         | 0.214 fair agreement | 0.086 |
| Nitrite |     | Negative | 6        | 12         |                   |       |
| Both leukocyte esterase and nitrite |     | Positive | 3        | 0          | 0.519 moderate agreement | 0.033* |
| Both leukocyte esterase and nitrite |     | Negative | 3        | 7          |                   |       |

\*< 0.05
Table 3: Diagnostic performance of urine dipstick test

| Urine dipstick | NIDRR       | 95% CI                  |
|---------------|-------------|-------------------------|
|               | UTI (n)     | No UTI (n)              | Sensitivity (%) | Specificity (%) | PPV (%)  | NPV (%)  | +LR     | −LR     |
| Leukocyte esterase |             |                         |                 |                |          |          |         |         |
| Positive      | 4           | 5                       | 19 (2-36)       | 86 (74-97)     | 44 (12-77) | 64 (50-78) | 1.33 (0.40-4.42) | 0.94 (0.74-1.21) |
| Negative      | 17          | 30                      |                 |                |          |          |         |         |
| Nitrite       |             |                         |                 |                |          |          |         |         |
| Positive      | 19          | 19                      | 90 (78-100)     | 46 (29-62)     | 50 (34-66) | 89 (74-100) | 1.67 (1.19-2.33) | 0.21 (0.05-0.82) |
| Negative      | 2           | 16                      |                 |                |          |          |         |         |
| Both leukocyte esterase and nitrite |         |                         |                 |                |          |          |         |         |
| Positive      | 3           | 2                       | 75 (33-100)     | 87 (69-100)    | 60 (17-100) | 93 (79-100) | 5.63 (1.37-23.01) | 0.29 (0.05-1.59) |
| Negative      | 1           | 13                      |                 |                |          |          |         |         |

NIDRR: National Institute on Disability and Rehabilitation Research; PPV: Positive predictive value; NPV: Negative predictive value; LR: Likelihood ratio; CI: Confidence interval; UTI: Urinary tract infection

reflected increasing the possibility that UTI was present like the former study. Consequently, the combined leukocyte esterase and nitrite urine dipstick test was good for UTI screening in SCI patients.

This is the first study that reported the interrater reliability of the urine dipstick between SCI patient's self-assessment compared to laboratory unit result. Although the validity of urine dipstick for UTI screening has been reported widely, results of these researches were different depending on population and gold standard test. This study was performed with SCI patients who had abnormal neurological function and used NIDRR as the gold standard test which was specific to UTI diagnosis in SCI patients. This study suggests that the combined leukocyte esterase and nitrite urine dipstick test may be preferable to help the SCI patients to screen UTI by themselves. Thereby, the primary care physicians and community health workers should promote the urine dipstick test for UTI screening in SCI patients which urine culture laboratory are not practical.

**Conclusions**

The interrater reliability of combined leukocyte esterase and nitrite urine dipstick test is moderate agreement. Besides the validity of combined leukocyte esterase and nitrite urine dipstick test is good for UTI screening in SCI patients. Therefore, the urine dipstick test should be promoted for UTI screening in SCI patients.

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**Conflicts of interest**

There are no conflicts of interest.

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