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Involvement of Urease-Producing Bacteria on Genital Skin in Community-Dwelling Women with Incontinence-Associated Dermatitis: A Cross-Sectional Study

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Purpose: Elevated skin pH facilitates the number of pathogenic bacteria increase, leading to the skin barrier dysfunction. This phenomenon is typically observed in individuals with Incontinence-associated dermatitis (IAD), which imposes a substantial physical and psychological burden on the afflicted individuals. We evaluated the association between the development of IAD in community-dwelling women with urinary incontinence and cutaneous urease-producing bacteria, as these bacteria may be involved in elevating skin pH by chemical reaction with urea in urine.

Patients and Methods: This was a cross-sectional study of 114 community-dwelling women with urinary incontinence who had registered for a survey campaign of a company. Swabs collected from genital skin were cultured in urea agar medium. The presence of urease-producing bacteria was determined by visually observing the change in the color of the culture medium caused by alkalization. The medium pH and total bacteria count were measured. Bacterial species were isolated and identified using a selective agar medium and simple identification kits. The participants were asked the presence of IAD by a self-administered questionnaire, and outcomes were compared between the IAD and no-IAD groups. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

Results: IAD was present in 31.6% (36/114) of participants. The detection rate of urease-producing bacteria and the medium pH was significantly higher in the IAD group than in the no-IAD group; however, the total number of bacteria was not significantly different. There were no significant between-group differences regarding the bacterial species identified.

Conclusion: The presence of urease-producing bacteria was associated with the development of IAD in community-dwelling women with urinary incontinence. Alkalization of the genital skin surface because of the contact between urine and urease-producing bacteria may compromise skin homeostasis. The bacterial species specifically involved in the development of IAD could not be determined.

Keywords: microorganism, perineal, pH, skin care, women's health

Introduction

Urinary incontinence, defined as the involuntary leakage of urine, can occur in both men and women at any age. This condition more commonly affects women and older adults due to the reduced tone and contractility of the perineal muscles.[1,2] The reported prevalence of urinary incontinence in community-dwelling adult women in the US, Europe, and Japan ranges from 26% to 62%.[2–4] A result from population-based study in United States showed that prevalence of urinary incontinence increases with age, from 8% for 30- to 39-year-old women to 33% for 80- to 90-year-old women.[5] A comprehensive systematic review and meta-analysis of observational studies reported that older age, obesity, diabetes, women's education, delivery rank, hypertension and smoking were the most important factors influencing the incidence of urinary incontinence in older women.[6] Urinary incontinence negatively impacts the quality of life of the affected

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individuals,[7] constrains their physical activity, induces anxiety about incontinence-related odor, and increases the risk of development of incontinence-associated dermatitis (IAD).[8–10]

IAD–a skin inflammation caused by persistent contact of urine or stool with genital skin–results in a compromised skin barrier, exposure to irritants including bacteria, and persistent inflammation and tissue damage to the vulva, perineum, perianal region, and buttocks.[10–12] Several studies have investigated the prevalence and risk factors for the development of IAD in hospitalized patients; however, there is a paucity of studies in community-dwelling women.[13–17] Findings from a cross-sectional study conducted in an Australian acute care hospital found an IAD prevalence of 10% among the entire patient and 42% among incontinent patients.[13] Of incontinent patient, IAD prevalence reported to be 8.4% in long-term care facilities to 19% in acute care facilities.[16] Age, smoking, diabetes, non-diaper use, longer hospitalization duration, and friction and shear problems are known to be major risk factors of IAD development, depending on the care settings.[15–17] These risk factors are demographic- or medicine related factors. IAD causes considerable discomfort, pain, burning sensation, and itching in the affected areas, decreasing the independence and quality of life of the afflicted individual.[18] Therefore, IAD belong to one of the most prevalent in incontinent women.

Healthy skin functions as a protective barrier, primarily through the presence of lipids and corneocyte cells. In the context of IAD, the two main factors that contribute to the disruption of skin barrier are considered to be elevated pH level and moisture.[19] Under normal homeostatic conditions, the stratum corneum of the epidermis maintains an acidic pH level of 4–6, which is conducive to the preservation and adherence of *Staphylococcus epidermidis*, a dominant bacterium of human skin microbiota. When the skin pH shifts into the alkaline range (pH > 7), there is a corresponding increase in the relative abundance of pathogenic bacteria. An experimental study involving the repeated application of alkaline urine on the arms of normal human volunteers resulted in skin irritation.[20] An increase in surface pH was associated with exacerbation of atopic dermatitis and heightened wound severity, likely due to its influence on bacterial growth.[21,22] Therefore, alterations in skin pH in the genital area play a significant role in the disruption of skin barrier.

We investigated the effect of urease-producing bacteria in the pathogenesis of IAD. Urease, a nickel-dependent metalloenzyme, catalyzes the hydrolysis of urea into carbon dioxide and ammonia. For some bacterial species, urease is an integral part of the bacterial acid response network, as its hydrolysis product ammonia is readily protonated into ammonium. This process entails the consumption of protons, increasing pH.[23] Urease is commonly observed in *Helicobacter pylori* isolated from patients with gastritis.[24] Some types of *Staphylococcus* spp. and gut bacteria (eg, *Proteus* spp. and *Klebsiella* spp) are capable of urea hydrolysis.[25,26] In our recent study, the presence of urease-producing bacteria was found to be associated with IAD development in hospitalized stroke patients. In that study, an original urea agar medium was used to detect urease-producing bacteria at genital sites.[27] We further reported a higher detection rate of *S. aureus* on genital skin sites in hospitalized stroke patients with IAD, compared to those without IAD.[28] However, there is a paucity of studies on community-dwelling women with urinary incontinence. The presence of urease-producing bacteria and the distribution of bacterial species may differ between hospitalized patients and community-dwelling women due to the differences in care settings.

The primary objective of this study was to evaluate the association between the development of IAD in urinary incontinent community-dwelling women and cutaneous urease-producing bacteria, which may be involved in elevating skin pH by chemical reaction with urea present in urine. As a secondary objective, bacterial species on the genital surface were isolated to identify the species involved in urease production. The research questions for this study were (1) is there a difference in the detection rate of urease-producing bacteria colonizing the genital skin between community-dwelling women with urinary incontinence who had IAD and those who did not have IAD?; and (2) do bacterial species isolated from genital skin differ between community-dwelling women with urinary incontinence who had IAD and those who did not have IAD?

Materials and Methods

Study Design and Participants

This was a cross-sectional study conducted in a Japanese university from July 2022 to June 2023. The study population was sampled from community-dwelling women who had already registered for a survey campaign of Nippon Paper

Crecia Co. Ltd. (Tokyo, Japan). The company manufactures and distributes paper- or fiber-based products such as incontinence pads. Individuals had voluntarily registered with the service with the understanding that various types of questionnaires and user tests may be distributed. The inclusion criteria for this study were (1) age > 20 years; individuals who had experienced urinary incontinence within the preceding year at the time of participating in this study; and (3) individuals using incontinence pads. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.[29]

To identify potential participants for this study, an employee of Nippon Paper Crecia sent letters to the 253 individuals who were selected by nonprobability sampling technique. The letter included the purpose, the experiment outline, required time to conduct testing, a consent form stating that the participant's personal information (name and address) would be shared with the researcher, and a return envelope. Individuals who had an interest for the participation were asked to send a reply letter within two weeks. The researcher received the reply letters from 126 individuals who were considered potential study participants, and then moved onto bacteria sampling and questionnaire described below.

Bacteria Sampling and Questionnaire

A document with information about the study procedures, the informed consent form, a sterilized cotton swab soaked in 10 mL of phosphate-buffered saline (PBS), a document containing instructions for swabbing the genital area using the cotton swab, a self-administered questionnaire, and a return envelope were sent to each participant.

Each participant swabbed the genital area to collect skin bacteria on the morning of the designated day. The participants were required to conduct swabbing before taking a shower and going to the toilet to minimize the effects of feces or skin cleaning. Participants first aseptically removed the swab with the squeezing part of the bottle to squeeze out excess saline; then, approximately 1×3 cm^2 area of perianal or genital skin was swabbed. The collected swabs were immediately immersed in PBS to maintain bacterial viability during transportation. Participants were instructed to avoid sampling bacteria during menstruation.

A self-administered reporting form was used to collect demographic and clinical characteristics of participants including the presence of IAD. The characteristics included age, height and weight for calculating body mass index, clinical history, use of antibiotics in the 2 weeks preceding sampling, and the use of incontinence pad. Participants were asked whether they had skin irritation on genital areas that came into contact with incontinence pads on the day of bacteria swabbing. If the irritation was present, the participants were further asked to circle the site of irritation on the illustration of the incontinence pad provided in the questionnaire. Based on the answer to this question, the researchers determined whether each participant had IAD or not, as described in the next section.

The swab sample and the completed questionnaires were required to be returned in an envelope within 2 weeks. A financial incentive (5,000 Japanese yen) was provided to each participant.

Definition of IAD

Skin irritation on the vulva, perineum, perianal region, and buttocks was defined as IAD. Skin irritation on the other areas (eg, skin sites of contact with the side gather of the pad for protection from urine leakage) was defined as no-IAD. Incontinence pads often damage the skin because of friction (rubbing) against the surface of the side gather of the pads. Skin irritation mainly caused by friction between the incontinence pad and the skin is currently not included in the definition of IAD.

Urease Detection

The original urea agar medium was prepared to detect urease-producing bacteria on the skin, as described in our previous report.[27] A solution consisting of 1 g of yeast extract, 1 g of polypepone, 0.2 g of glucose, 1 g of sodium chloride, 0.4 g of potassium hypophosphite, 0.0024 g phenol red, and 3.0 g of agar, diluted with 200 mL of distilled water was prepared and autoclaved. Separately, 4 g of urea was dissolved in 10 g of distilled water (initial concentration: 6.67 mol/L) and stored for sterilization in an ultraviolet chamber for 1 hour. The two solutions were mixed and adjusted to a pH of 6.7 ± 0.2. Subsequently, 10 g of the mixed solution was poured into a dish (diameter = 90 mm) to obtain the urea agar

medium. All chemicals used in preparing the urea agar medium were purchased from FUJIFILM Wako Pure Chemical Corp., Japan.

The presence of urease-producing bacteria, which convert urea into ammonia, was determined by visually observing the change in color of the urea agar medium (from yellow to bright pink) caused by its alkalization. After the collected swabs were transported to the laboratory, the head of the swabs immersed in PBS was transferred to a 2-mL aliquot of sterile PBS and vortexed for urease detection. Fifty microliter of each solution was poured and spread onto the urea agar medium, and the medium was incubated aerobically at 37°C overnight. The degree of urease activity was categorized as "strong", "weak", or "almost none/none".

Measurement of pH

A pH meter (LAQUA-22 pH meter, HORIBA Ltd., Kyoto, Japan) was used to confirm that the increase in the pH on the surface of the agar medium corresponded to the change in color of the agar medium with bacterial cultivation (including urease-producing bacteria).

Bacterial Counts

For bacterial count measurement, the bacterial suspension in the swabs was 10-fold diluted, and 50 μL of each dilution was spread onto the trypticase soy agar medium (Eiken Chemical, Tokyo, Japan). After overnight aerobic incubation at 37°C, viable bacteria were measured by counting the number of visible bacteria (colony-forming unit, CFU) per agar plate.

Species Identification

The detailed procedure for the isolation and identification of species is described in our previous study.[28] Briefly, species were isolated using selective agar media such as Mannitol Salt Agar (Becton Dickinson, Tokyo, Japan) and CHROMagar™ Orientation (Becton Dickinson), after using trypticase soy agar with 5% sheep blood (Becton Dickinson). Staphylococcal strains were identified using the N-ID test SP-18 (Nissui Pharmaceutical, Tokyo, Japan). N-ID test ED-20 (Nissui Pharmaceutical) was applied to identify Gram-negative rods such as *Escherichia coli, Proteus* spp., and *Klebsiella* spp. Furthermore, Gram-stain characteristics were confirmed for all strains.

Statistical Analysis

The prevalence of IAD was calculated by dividing the total number of IAD cases by the total number of study participants. Outcomes were compared between participants with or without IAD (IAD group and no-IAD group, respectively). Continuous variables were expressed as mean ± standard deviation (SD) and categorical variables were expressed as frequency (percentage). Between-group differences with respect to urease activity and the identified bacterial species were assessed for statistical significance using the chi-square test. Data regarding the pH on the surface of the agar medium and the total bacterial count were expressed as median and interquartile range (IQR) and compared using the nonparametric Mann–Whitney *U*-test. A p-value of < 0.05 was considered indicative of statistical significance. All statistical analyses were conducted using the Statistical Package for the Social Sciences version 28.0 (IBM Corporation, Armonk, NY, USA).

Results

Clinical Characteristics of the Study Population

IAD was present in 31.6% (36/114) of the study population. There were no significant differences between the IAD and no-IAD groups with respect to age or any of the clinical characteristics (Table 1).

Urease Detection

Representative photographs of the urea agar medium after bacterial cultivation are shown in Figure 1. The urease activity was classified into three categories (strong, weak, and almost none/none) based on the degree of color change in the agar

Table 1 Clinical Characteristics of the Study Population

Characteristics	Overall (n = 114)	IAD (+) (n = 36)	IAD (−) (n = 78)	*P*-value
Age (years), mean ± SD	64.4 ± 10.8	62.3 ± 10.0	65.3 ± 11.1	0.17
Body mass index, mean ± SD	26.8 ± 5.1	27.5 ± 5.5	26.5 ± 4.9	0.32
Clinical history, n (%)				
Diabetes mellitus, yes	31 (27.4)	11 (31.4)	20 (25.6)	0.52
Hypertension, yes	62 (54.4)	18 (50.0)	44 (56.4)	0.52
Constipation, yes	27 (23.9)	8 (22.9)	19 (24.4)	0.86
Antibiotic use, yes, n (%)	3 (2.6)	2 (5.6)	1 (1.3)	0.19
Use of incontinence pad				
Duration, n (%)				0.95
<4 years	14 (12.3)	4 (11.1)	10 (12.8)	
≥4 and <6 years	42 (36.8)	13 (36.1)	29 (37.2)	
≥6 years	58 (50.9)	19 (52.8)	39 (50.0)	
Frequency, n (%)				NC
Everyday	111 (97.4)	36 (100)	75 (96.2)	
2 or 3 days a week	2 (1.8)	0 (0)	2 (2.6)	
Several a month	1 (0.9)	0 (0)	1 (1.3)	
Required quantity, n (%)				0.43
<2 pads/day	11 (9.6)	5 (13.9)	6 (7.7)	
≥2 and <4 pads/day	46 (40.4)	12 (33.3)	34 (43.6)	
≥4 pads/day	57 (50.0)	19 (52.8)	38 (48.7)	

Notes: Between-group differences in each characteristics were assessed for statistical significance using the non-paired *t* test for continuous variables and the chi-square test for categorical variables, respectively.
Abbreviations: NC, not calculated; IAD, incontinence-associated dermatitis; SD, standard deviation.

medium from yellow to bright pink. The urease activity in the IAD group was significantly stronger than that in the no-IAD group ($p = 0.003$) (Table 2).

Measurements of pH

The median (IQR) pH on the surface of the agar medium in the IAD group was significantly greater than that in the no-IAD group (8.7 [7.8–9.2] and 7.6 [7.1–8.5], respectively; $p = 0.0003$) (Figure 2).

Bacterial Counts

The number of CFUs was not significantly different between the IAD and no-IAD groups ($p = 0.07$) (Figure 3).

Species Identification

Bacterial analysis detected 54 species in the 36 swabs of the IAD group and 98 species in the 78 swabs of the non-IAD group. There were no significant between-group differences with respect to any of the identified bacterial species (Table 3). However, the detection rate of *E. coli* in the IAD group tended to be lower than that in the non-IAD group. Furthermore, the detection rate of *K. pneumoniae* and *P. mirabilis* (strong urease producers) tended to be higher in the IAD group. Regarding *Staphylococcus* spp., *S. aureus* was the most commonly detected in both groups and only a few coagulase negative *Staphylococcus* (CNS), including *S. epidermidis*, were detected.

Discussion

Studies on the prevalence and risk factors to identify individuals of developing IAD have been widely reported in various clinical settings.[13–17] However, these studies have been conducted on patients admitted to hospitals or long-term care facilities. In addition, only demographic or medical-related risk factors of IAD have been investigated, but exploring

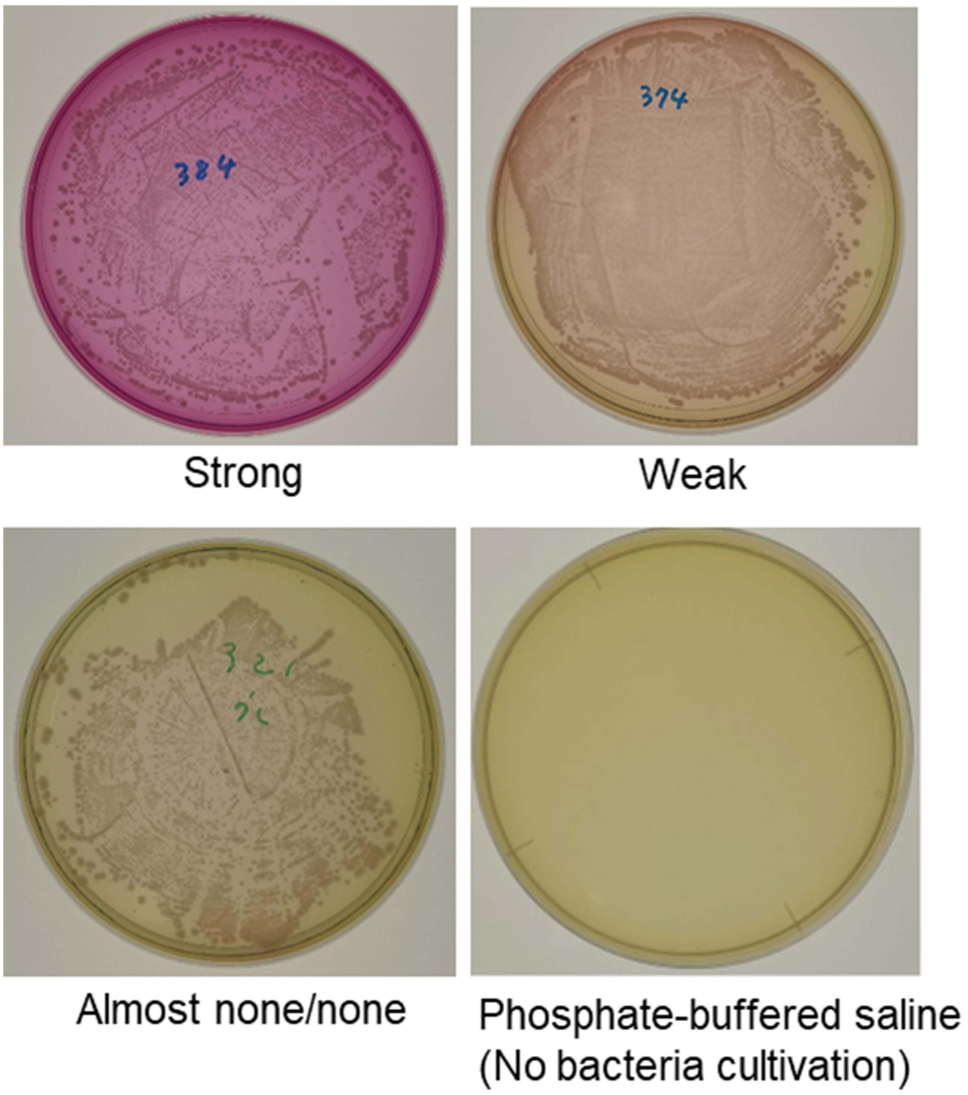

Figure 1 Representative photographs of the urea agar medium after bacterial cultivation. The urease activity was categorized as strong, weak, and almost none/none based on the change in the color of the medium (from yellow to bright pink).

biological risk factors yet to be adequately provided. In this study, the authors aimed to clarify the association between the development of IAD and cutaneous urease-producing bacteria in community-dwelling women with urinary incontinence. The present study is the first to demonstrate a difference in the detection rate of urease-producing bacteria colonizing the genital skin between community-dwelling women with urinary incontinence who had IAD and those who did not have IAD. Our data may help clarify the mechanism of the pathogenesis of IAD. Moreover, our findings may enable early identification of individuals who are at risk of IAD, and help inform preventive interventions for community-dwelling women from a biological perspective.

Table 2 Comparison of the Urease Activity Between the Two Groups

Urease Activity	Overall (n = 114)	IAD (+) (n = 36)	IAD (−) (n = 78)	*P*-value
Strong, n (%)	53 (46.5)	25 (69.4)	28 (35.9)	0.003
Weak, n (%)	31 (27.2)	7 (19.4)	24 (30.8)	
Almost none/none, n (%)	30 (26.3)	4 (11.1)	26 (33.3)	

Notes: Between-group differences were assessed for statistical significance using the chi-square test.
Abbreviation: IAD, incontinence-associated dermatitis.

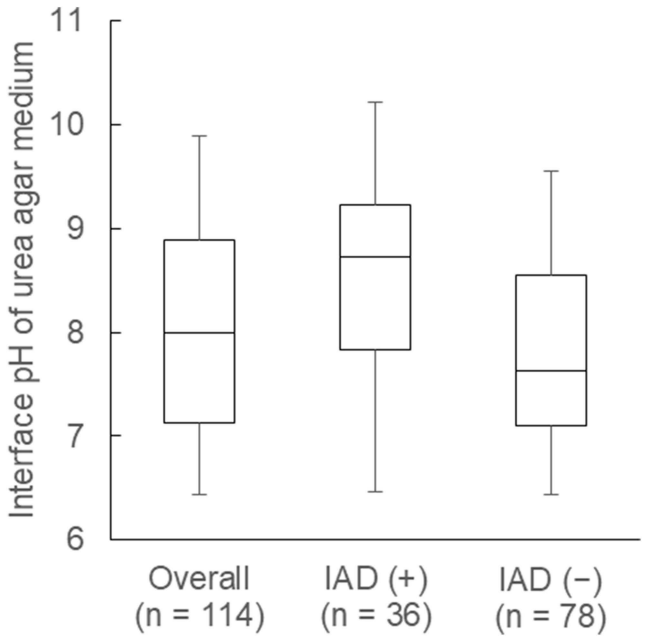

Figure 2 Box plots of the pH value of the urea agar plate in the IAD group (IAD+) and no-IAD group (IAD−). Between-group differences were assessed for statistical significance using the nonparametric Mann–Whitney *U*-test.

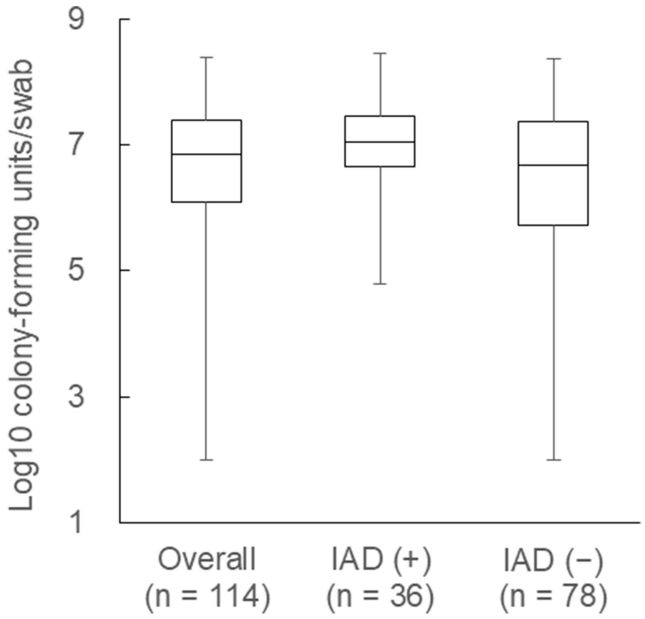

Figure 3 Comparison of bacterial growth in the IAD group (IAD+) and no-IAD group (IAD−). Between-group differences were assessed for statistical significance using the nonparametric Mann–Whitney *U*-test.

The most notable finding of this study was the significantly higher detection rate of urease-producing bacteria in the IAD group even though the total number of bacterial colonies was not significantly different between the two groups (Table 2, Figure 3). Our data support the hypothesis that urease-producing bacterial colonization is associated with IAD development in community-dwelling women with urinary incontinence. In the previous study involving hospitalized stroke patients, 30.3% of swabs from the IAD group were categorized as "strong" in terms of urease-producing capacity, compared to only 5.9% in the no-IAD group.[27] In the present study, the detection rate of "strong" urease-producing capacity was 69.4% and 35.9% in the IAD group and no-IAD group, respectively (Table 2). While the previous study

Table 3 Comparison of the Bacterial Species Identified Between the IAD Group and No-IAD Group

Number of participants Number of bacterial species	Overall (n = 114) (n = 151)	IAD (+) (n = 36) (n = 54)	IAD (−) (n = 78) (n = 98)	*P*-value
Gram-positive				
Staphylococcus aureus	7 (4.6)	3 (5.6)	4 (4.1)	0.68
Staphylococcus epidermidis	3 (2.0)	0 (0)	3 (3.1)	NC
Staphylococcus caprae	2 (1.3)	1 (1.9)	1 (1.0)	0.67
Staphylococcus simulans	2 (1.3)	0 (0)	2 (2.0)	NC
Staphylococcus haemolyticus	1 (0.7)	0 (0)	1 (1.0)	NC
Staphylococcus xylosus	1 (0.7)	1 (1.9)	0 (0)	NC
Staphylococcus lugdunensis	1 (0.7)	1 (1.9)	0 (0)	NC
Gram-negative				
Escherichia coli	41 (27.2)	10 (18.5)	31 (31.6)	0.08
Klebsiella pneumoniae	11 (7.3)	6 (11.1)	5 (5.1)	0.17
Proteus mirabilis	8 (5.3)	4 (7.4)	4 (4.1)	0.38
Morganella morganii	7 (4.6)	3 (5.6)	4 (4.1)	0.68
Enterobacter aerogenes	6 (4.0)	3 (5.6)	3 (3.1)	0.45
Klebsiella oxytoca	4 (2.6)	1 (1.9)	3 (3.1)	0.66
Raoultella ornithinolytica	4 (2.6)	2 (3.7)	3 (3.1)	0.83
Salmonella enterica	3 (2.0)	1 (1.9)	2 (2.0)	0.94
Citrobacter koseri	2 (1.3)	1 (1.9)	1 (1.0)	0.94
Tatumella ptyseos	2 (1.3)	0 (0)	2 (2.0)	NC
Serratia marcescens	2 (1.3)	0 (0)	2 (2.0)	NC
Serratia liquefaciens	2 (1.3)	1 (1.9)	1 (1.0)	0.94
Escherichia hermannii	1 (0.7)	0 (0)	1 (1.0)	NC
Salmonella bongori	1 (0.7)	0 (0)	1 (1.0)	NC
Proteus vulgaris	1 (0.7)	1 (1.9)	0 (0)	NC
Enterobacter cloacae	1 (0.7)	0 (0)	1 (1.0)	NC
Citrobacter freundii	1 (0.7)	1 (1.9)	0 (0)	NC
Others	37 (24.5)	14 (25.9)	23 (23.5)	0.74

Notes: Between-group differences were assessed for statistical significance using the chi-square test.
Abbreviations: NC, not calculated; IAD, incontinence-associated dermatitis.

investigated hospitalized stroke patients regardless of sex or type of incontinence (fecal or urinary incontinence or both), the present study exclusively focused on women with urinary incontinence. This precludes a direct comparison of the detection rate with the previous study; however, this suggests that the alkalization of the genital skin surface because of the contact between urine and urease-producing bacteria is likely involved in compromising skin homeostasis.

We could not identify the bacterial species that were significantly involved in urease production. In a previous study of hospitalized stroke patients, *S. aureus* was detected in 50.7% of patients in the IAD group, and only 17.9% of patients in the no-IAD group ($p = 0.0029$).[28] Conversely, in this study, *S. aureus* was rarely detected in both groups, and various types of Gram-negative bacteria species were found on the genital skin, with most of the species belonging to the family Enterobacteriaceae. *Proteus* spp, *K. pneunomae*, and *Morganella morganii* are strong urease producers while *E. coli* is not.[30] In the present study, the detection rates of *P. mirabilis* and *K. pneumoniae* were higher in the IAD group than in the no-IAD group, but the difference was not statistically significant (Table 3). We recognize that colonization of the genital skin by these enteric bacteria can potentially affect the development of IAD. Humans have a symbiotic relationship with their skin microbiota (a complex community of bacteria, fungi, and viruses that live on the skin surface), which act as a protective barrier for the body.[31] A recent study applied metagenomic DNA sequencing techniques to assess the taxonomic diversity of microorganisms associated with the skin.[32] According to a recent narrative review, the development of diaper dermatitis is associated with a change in the composition of the skin microbiome from its normal state.[33]

Future studies should employ sequence-based microbiome analysis techniques to identify the bacterial species associated with the development of IAD.

Skin pH may be used as a marker of physiological state, especially for assessing the structural integrity of skin. However, its application for assessing dermatitis at genital sites is currently in the research phase. Currently, skin pH is measured in clinical settings only in specific contexts, such as in infants.[34] Skin pH measurement is typically affected by environmental factors such as humidity and temperature; therefore, it should be measured under controlled conditions. The urea agar medium in this study can be used irrespective of the surrounding microclimate, suggesting its potential use for predicting the risk of IAD development in community-dwelling women (Figure 2).

The high prevalence of IAD in this study (31.6%) suggests that IAD is a prevalent and underappreciated skin condition in community-dwelling women. The mean age of participants in this study was > 60 years. The frequency of urinary incontinence increases significantly in older adults, increasing the risk of developing IAD. Our future research would focus on developing a novel solution for IAD preventive care in community-dwelling women with urinary incontinence aimed at reducing urease-producing bacteria on genital skin sites.

This study had several limitations. First, the cross-sectional study design prevented the evaluation of a cause-effect relationship between the presence of urease-producing bacteria and IAD development. A prospective study is required to clarify the role of urease-producing bacteria in the causation of IAD in individuals who are incontinent due to various diseases. Second, the authors did not perform a power calculation to estimate the appropriate sample size because the number of an accurately estimated population could not be set before the start of this study. Our analysis might be underpowered but the authors believe that a sample size of > 100 participants should be sufficient to achieve the objectives of this cross sectional study. Third, although a document containing instructions for swabbing the genital area using the cotton swab was sent to the study participants, it was difficult to confirm that the participants collect swab in a correct manner. Swab sample collection technique may affect the result of this study. The reliability of a bacteria swab sample is thought to be affected by several factors, including operator technique, environmental factors, and sample quality. Swab samples should have been repeatedly collected from each study participant at the same time or on different days to verify the reliability of our test results, such as the involvement of urease-producing bacteria, bacterial species distribution, and total bacterial counts on the genital skin. Finally, visual inspection by wound care professionals to assess the presence of IAD and its severity would have been ideal. However, direct inspection of the study participants at their homes is difficult due to ethical and legal considerations.

Conclusion

In conclusion, the presence of urease-producing bacteria at genital sites was associated with IAD development in community-dwelling women with urinary incontinence. Bacterial species distribution and total bacterial counts on the genital skin did not significantly differ between subjects with and without IAD.

For the broader implication of our research findings, more appropriate skin assessment for IAD preventive measures should be required to improve quality of life in community-dwelling women. However, techniques for assessing skin integrity by themselves on their genital sites at their home have not yet been established. The authors believe that our urease-producing bacteria detection technique may be applicable to the identification of individuals at high risk of developing IAD, as a novel point-of-care IAD assessment piece of technology in a home.

For the strength of this study, this is the first to represent that the presence of urease-producing bacteria be a risk factor for the development of IAD on the genital skin surface in community-dwelling women, by using our original urea agar medium for the detection of urease-producing bacteria. For the weakness and study limitations, we recognized that study participants were not selected by random sampling, that swab sample collection techniques affected the reliability of our test results, and that the authors did not perform power analysis for sample size determination. As a future perspective, reliability testing for involvement of urease-producing bacteria and identification of bacterial species distribution is needed to ensure our hypothesis and data stability. Using point-of-care techniques to identify individuals at risk of developing IAD in a community will contribute to minimizing the reduction of their quality of life in their daily lives due to the development of IAD.

Data Sharing Statement

The dataset used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Informed Consent

This study was approved by the Institutional Review Board of Fujita Health University (approval number HM21-412). Written informed consent was obtained from all participants. All aspects of this research were performed per the principles set forth by the Declaration of Helsinki. All participants' data were kept confidential.

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Author Contributions

All authors participated in the conception and design of this study. M.K. was responsible for data collection, data analysis, and interpretation of the results. All authors contributed to the drafting of the manuscript and critical revisions for important intellectual content and gave their final approval for the version to be published. Finally, all authors agreed to be accountable for all aspects of this work to ensure that questions related to the accuracy or integrity of any part of this work will be appropriately investigated and resolved.

Disclosure

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