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Major Article

Effectiveness of two bed bath methods in removing microorganisms from hospitalized patients: A prospective randomized crossover study

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Key Words:
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Background: Few studies have compared the effectiveness of washing with either soap and water or disposable wet wipes. The objective of this study was to compare the effectiveness of washing with either soap and water or disposable wet wipes in reducing microorganisms in the groin and perineum of hospitalized patients, which could potentially reduce the risk of hospital-acquired urinary tract infections.

Methods: In this crossover, block-randomized trial, skin swabs from the groin and perineum areas of patients were obtained before and after these areas were washed with either soap and water or disposable wet wipes. Columbia agar plates and CHROMagar Orientation Medium (Becton Dickinson; Franklin Lakes, NJ) and matrix-assisted laser desorption/ionization time-of-flight mass spectrometry procedures were used to identify species of microorganisms.

Results: Fifty-eight paired skin swabs were obtained. Both washing methods resulted in a statistically significant reduction in the amount of all microorganisms, including microorganisms with the potential to cause urinary tract infections. New species were observed after using both washing methods. No statistically significant difference in the removal of microorganisms was observed between the two washing methods.

Conclusions: The two washing methods appear to be equally efficient in removal of microorganisms in the groin and perineum areas, including microorganisms that potentially could cause hospital-acquired urinary tract infections.

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Author contributions: P.L.V. collected all the data and takes full responsibility for the integrity of the data and the accuracy of the data analysis. P.L.V., C.S.J., J.S., M.C., and J.P. contributed to the study design; analysis and interpretation of the results; and drafting the manuscript and have all approved the final manuscript.

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BACKGROUND

Hospital-acquired urinary tract infections (HAUTIs) are among the most common hospital-acquired infections¹⁻³ and affect an estimated 15,000 to 20,000 patients per year in Danish hospitals.³ It has been estimated that 15% to 25% of all somatic patients have indwelling catheters, which may account for up to 80% of all HAUTIs.^{2,3} For patients with HAUTIs, discomfort, pain, and complications are frequent,²⁻⁴ and HAUTIs may impose additional health care costs.⁵

The majority of HAUTIs are caused by pathogens from the urethral meatus and by patients' normal flora.^{3,4} Many interventions are available to reduce the risk of HAUTIs,^{1,3,4} including performing intimate hygiene.² Most guidelines for intimate hygiene for patients with indwelling catheters, including the national Danish guideline,

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recommend one daily intimate wash with soap and water (SAW) or disposable wet wipes (DWW). $^{1-3}$

An American study on the use of bed baths for inpatients with indwelling catheters found that the SAW method was more frequently used than DWWs for intimate hygiene. The choice is generally made by the nursing staff based on an individual patient's actual situation, time available on the ward, and the staff's personal preferences and experiences.

In Danish hospitals, the use of SAW is increasingly being replaced by the use of DWWs.⁷ DWWs may offer advantages over SAW; for example, the risk of contamination can be higher with the use of SAW than with DWWs because the bath basin may become contaminated during the washing process^{8,9} and become a potential source of infection.¹⁰ The use of DWWs may leave the patient's skin feeling softer and better moisturized than after washing with SAW.¹¹ DWWs have been shown to be associated with enhanced skin barrier function and reduced risk of skin impairment, dermatitis, and pressure ulcers.^{12,13} In addition, the use of DWWs has been found to reduce staff time and save costs.^{7,8}

Only 3 studies have compared the effectiveness of SAW and DWWs in reducing microorganisms (MOs) on the skin. 8.9.14 Two of these studies found that both types of bath were equally effective in reducing MOs. 8.14 The amount of MOs was reduced after the use of both SAW and DWWs, 8.9.14 but two of the studies found increased numbers of species, indicating new contamination after washing with SAW and DWWs. 8.14 With increased use of DWWs in Danish hospitals, it is relevant to compare the effectiveness of SAW and DWWs in reducing MOs. The objective of this study was to compare the effectiveness of SAW and DWWs in reducing MOs in the groin and perineum areas of hospitalized patients, thus also potentially reducing the risk of HAUTIS.

METHODS

Study design

A randomized, crossover design was used in this study. The two interventions were washing with DWWs or SAW. Washing with SAW was performed with soap (containing sodium laureth sulfate, disodium, laureth sulfosuccinate, sodium chloride, cocamide DEA, glycerin, malic acid, sodium benzoate, glycol distearate, sodium hydroxide, steareth-4), water, washcloths, basins, and towels. Washing with DWWs was performed using packaged disposable wet wipes. Each pack included eight individually wrapped wet wipes. The ingredients included water, glycerin, decyl glucoside, glucolactone, sodium benzoate, calcium gluconate, *Aloe barbadensis* extract, *Chamomilla* recutita extract, caprylic acid, capric triglyceride, and tocopnenyl acetate. The materials and tools used for both washing methods were standard for the hospital.

Participants were randomized to a random sequence of the two washing methods. Group A had intimate hygiene with SAW on day one and with DWW on day two; group B had intimate hygiene with DWWs on day one and with SAW on day two. Block randomization was accomplished using sequentially numbered, opaque, sealed envelopes that assigned participants to either group A or group B. The block size was four, which allowed for six possible combinations of the randomization. ¹⁵ The envelopes were prepared by an independent secretary.

Participants

Three wards (an intensive care unit, a medical ward, and a surgical ward) in a Danish university hospital were identified by the hospital purchasing manager as the wards with most frequent use of DWW. Prior to the recruitment of patients, meetings were held with the

Table 1 Selection criteria

Inclusion criteria	Exclusion criteria
Patients >18 y of age	Patients with diarrhea
Patients in need of help with intimate hygiene	Patients in isolation.
Patients hospitalized for a minimum of 2 consecutive days	Terminal patients
Patients able to understand oral and written information	Patients waiting for elucidation
Patients able to sign a written consent for the study	Patients already washed
	Patients did not want to participate

head nurses at each of these wards. Subsequently, oral and written information about the study was provided to the nursing staff. Furthermore, instructions for intimate hygiene in accordance with the hospital guidelines¹⁶ were provided to the staff in advance of washing and were repeated during washing. The nursing staff identified eligible patients who needed help with intimate hygiene during the morning tasks and asked the patients for oral consent to hear more about the study. Oral and written information was provided to interested patients, and written consent was collected in accordance with the inclusion criteria (Table 1). Randomization of patients occurred immediately after inclusion.

Data collection

Skin swabs from each participating patient were obtained before and after washing with SAW or DWWs from one side of the groin and the perineum. MOs from these skin sites may potentially cause HAUTIS, and both sites are prone to MO growth. The same side of the groin was used on both days, and the same person obtained all of the skin swabs using aseptic techniques with sterile equipment and hospital guidelines for skin swabs, transportation, and storage. An area 3 cm \times 3 cm was swabbed with a moist sterile cotton swab. Each swab was placed in Stewarts' medium and transported to the Department of Clinical Microbiology at the study hospital. Blinded cultivation, inspection, and qualitative classical microbiological analyses were performed in accordance with regional guidelines. 16

All swabs were cultured on Columbia III agar plates with 5% sheep's blood (Becton Dickinson; Franklin Lakes, NI)¹⁸ and incubated 20 to 24 hours in a 35°C-37°C aerobic atmosphere. The inoculated plates were assessed by counting colony-forming units (CFUs) and determining colony size and hemolytic reactions of the MOs present. The swabs were also cultured on CHROMagar Orientation Medium (Becton Dickinson), which is a non-selective medium for isolation, direct identification, differentiation, and enumeration of urinary tract pathogens and for presumptive identification of many other pathogens. 16,19 The culture was examined using guidelines for identification based on different colony colors. Finally, species of MOs were validated using matrix-assisted laser desorption/ionization time-offlight mass spectrometry. 16 Demographic and medical characteristics were obtained for all participants using medical records and researcher observations, as well as directly from the participants (Table 2).

Statistical analysis

Non-parametric tests were used based on assessment of the distribution of the data.²⁰ Statistical analyses were performed using Stata/IC 15.1 (StataCorp; College Station, TX). Significance level was set at 95% All identified MOs were included in the analysis. The

P.L. Veie et al. / American Journal of Infection Control 00 (2019) 1-6

Table 2Demographic and medical characteristics of study participants

Variable	All participants (N = 72)	Participants with paired data (N = 58)	Participants with microbes with the potential to cause urinary tract infections (N = 70)	Participants with Escherichia coli (N = 36)
Female/male, n	35/37	28/30	34/36	18/18
Age (y), median (range)	76 (38-98)	77 (38-96)	77 (38-98)	77 (43-98)
Length of stay (d), median (range)	5 (1-93)	6 (1-79)	6 (1-93)	5 (1-93)
Diabetes, n (%)	27 (38)	23 (40)	27 (38)	33 (30)
Urinary catheter, n (%)	49 (68)	38 (66)	49 (68)	25 (69)
Diaper, n (%)	65 (90)	52 (90)	65 (90)	33 (91)
Wound, n (%)	29 (40)	27 (47)	29 (40)	14 (39)
Stoma, n (%)	11 (15)	11 (17)	11 (15)	6 (16)
Skin problems, n (%)	21 (29)	20 (35)	21 (29)	11 (31)
Surgery, n (%)	19 (26)	17 (29)	19 (26)	9 (25)
Diagnosis, n (%)*				
Elucidation	12 (17)	9 (16)	12 (17)	8 (22)
Infection	17 (24)	13 (22)	17 (24)	6 (17)
Cancer	6(8)	4(7)	6 (8)	1 (3)
Surgical	9 (13)	9 (16)	9 (13)	6 (17)
Medical	16 (22)	14 (24)	16 (22)	9 (25)
Other	12 (17)	9 (16)	12 (17)	6 (17)
Antibiotics				
Treated, n (%) [†]	27 (38)	22 (38)	27 (38)	14 (36)
Length of treatment (d), median (range)	4.3 (1-11)	4.2 (1-7)	4.3 (1-11)	4.7 (2-11)
Broad-spectrum antibiotics, n (%)	8 (30)	5 (23)	8 (30)	6 (43)

^{*}Diagnosis reflects the reason for the actual admission.

number of CFUs for each species of MO was categorized by qualitative assessment at the Department of Clinical Microbiology as few ($\leq 10^4$ CFUs), some (10^4 - 10^5 CFUs), or many ($\geq 10^5$ CFUs). For the statistical analysis, the category of "few" was assigned the value 1, "some" was assigned the value 2, and "many" was assigned the value 3 on an ordinal dimensionless scale. For each participant, the amounts of the different MOs were summarized before and after each washing method (Table 4). In the analysis, two variables were used: the amounts of MOs, represented as the sum of the ordinal scale, and the number of MO species present on the skin. If a MO species was identified only after washing, it was assigned 0 before washing. In the summarized paired analysis, the change in total amounts of MOs was recoded as 0 (same and increase) or 1 (decrease). The interaction (carryover effect)²¹ between sequences (AB or BA) was included as a dependent variable in a logistic regression analysis.

For summarized MOs (paired data), the Wilcoxon matched-pairs signed-rank test²¹ was used to analyze if a difference could be observed in the amount of all MO and for species that could potentially cause HAUTIs, between the use of SAW and DWWs, and after washing with SAW or DWWs. The 2-sample Wilcoxon rank-sum test (Mann-Whitney *U*-test) was used to analyze whether or not a difference could be observed between the use of SAW and the use of DWWs with regard to the amounts of *Escherichia coli*.

Power calculation

Before conducting the actual study, a pilot study was performed to calculate the appropriate sample size for comparing the two methods. The pilot study included 10 patients from two wards. The power calculation estimated that 62 participants would be needed to obtain a power of 80% and alpha value less than 5% to reject the null hypothesis that there would be no difference in the reduction of the amounts of MOs between washing with the use of SAW or DWWs. A difference of 1 on the ordinal scale was considered to be a minimal clinically important difference.

Ethical considerations

This study was performed according to the ethical guidelines for nursing research in the Nordic countries²² and guidelines developed by the World Medical Association implemented by the Danish National Ethics Committee. The study was registered at ClinicalTrials. gov (NCT02984527; SDUSF-2015-65/RI-(205)). The local scientific ethics committee confirmed that formal ethical registration and approval were not required. The head physicians at the 3 participating wards approved the study. Formal permission to store the data was obtained by the Danish Data Protection Agency (J.No.18/35356).

RESULTS

Out of 284 potentially eligible patients, 72 participants were included in the study during dayshifts between November 2016 and February 2018. In total, 130 skin swabs were obtained (58 paired samples and 14 single samples). The same staff washed on both days in 31 out of 58 patients. The characteristics of the study participants are shown in Table 2. Five participants who met the inclusion criteria declined to participate, and 14 patients dropped out because they got diarrhea (n = 6), became isolated (n = 2), received topical treatment (n=1), were discharged (n=3), or had already been washed before intervention on day 2 (n = 2). The dropout rate was 20%. Those who dropped out used a urinary catheter more frequently (n = 11; 79%)and were more often treated with antibiotics (n = 6; 43%), including broad-spectrum antibiotics (n = 3; 21%) than those who completed the study (Fig 1). No statistically significant difference was found between group A and group B when testing for carryover effect. In total, 42 different species of MOs were identified before and after washing.

For paired data, the number of species of MOs identified (from both days and skin sites) on a participant varied from 3 to 8. On average, the participants had 5.5 species of MOs on the skin. Contamination with new species of MOs after washing was observed after both washing methods. For paired data, the number of species of MOs

[†]Patients were being treated with antibiotics when swabs were obtained.

P.L. Veje et al. / American Journal of Infection Control 00 (2019) 1-6

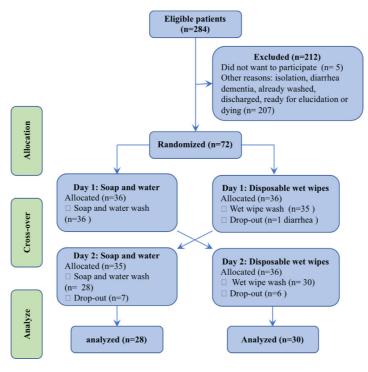


Fig 1. Flow chart.

increased from 320 to 329 in all of the swab samples after washing with SAW and from 317 to 329 after washing with DWWs. However, in the paired analysis, the amounts of MOs (1, 2, or 3 on an ordinal scale) in all of the swap samples decreased from 615 to 503 after washing with SAW and from 579 to 480 after washing with DWWs (Table 3). A sensitivity analysis of the paired swab samples collected in the groin showed a decrease in the amounts of MOs from 302 to 235 after washing with SAW and from 292 to 236 after the use of

DWWs. In the perineum, a decrease from 313 to 268 was observed in the amounts of MOs after washing with SAW and from 287 to 244 after washing with DWWs.

The analysis for paired data showed that the summarized amounts of MOs were reduced 1 to 13 after washing with SAW and 1 to 12 after washing with DWWs for some participants. For other participants, the amounts of MOs increased 1 to 4 after washing with SAW and 1 to 5 after washing with DWWs (Table 4). Reductions in

Table 3Total number and amount of microbe species before and after washing with soap and water or disposable wet wipes

	Soap and water			Disposable wet wipes				
Number and amount of microbe species	Before	After	Paired*	n [†]	Before	After	Paired*	n [†]
Total microbes								
Number of microbe species [‡]	320	329	410	58	317	329	376	58
Amount of microbes§	615	503	410	58	579	480	376	58
Microbes in the groin								
Number of microbe species [‡]	158	158	198	58	158	163	184	58
Amount of microbes§	302	235	198	58	292	236	184	58
Microbes in the perineum								
Number of microbe species [‡]	162	171	212	58	159	166	192	58
Amount of microbes [§]	313	268	212	58	287	244	192	58
Microbes potentially causing urinary tract infections								
Number of microbe species [‡]	316	339	410	70	279	291	336	60
Amount of microbes§	603	522	410	70	504	424	336	60
E coli [¶]								
Number of <i>E coli</i> [‡]	38	44	50	34	28	31	33	24
Amount of E coli§	60	55	50	34	39	34	33	24

^{*}The number of paired microbes is higher than the number of microbes before and after because some of the species of microbes were 0 before and after.

[†]Number of participants

[‡]How many times the species of microbes were present on the skin.

[§]Amount of microbes (summarized as 1, 2, or 3 on an ordinal scale).

Amount of the 22 identified species of microbes with the potential to cause urinary tract infections and used for statistical analysis.

Identified Escherichia coli used for statistical analysis.

Table 4Change in summarized amount of microbes after washing with soap and water or disposable wet wipes

Amount of microbes	Soap and water (N=58)	Disposable wet wipes (N=58)
Increase	19%*	22%*
5	0	1
4	2	0
3	1	3
2	2	6
1	6	3
Same [†]	14% [†]	$10\%^{\dagger}$
0	8	6
Reduction, total	67% [‡]	67% [‡]
1	13	11
2	10	10
3	5	7
4	1	4
5	2	2
6	2	0
7	0	2
8	2	1
9	2	0
10	0	1
11	1	0
12	0	1
13	1	0
Means (summarized MO)		
Before intervention	10.6	10.0
After intervention	8.7	8.3
P value	.0001	.0148

^{*}Percent of participants with an increase after washing.

the amounts of MOs were observed in 39 of 58 participants after washing with SAW (67%) and in 39 of 58 participants after washing with DWWs (67%). An increase in the amounts of MOs was seen in 11 of 58 participants after washing with SAW (19%) and in 13 of 58 participants after washing with DWWs (22%) (Table 4).

The analysis showed a significant reduction in the amounts of MOs after washing with both SAW (P=.0001) and DWWs (P=.0148) for the paired data. A sensitivity analysis showed that there was no statistically significant difference in the reduction of amounts of MOs between the groin and perineum areas for either SAW (P=.65) or DWWs (P=.15). Furthermore, there was no statistically significant difference (P=.84) in the reduction of amounts of MOs between SAW and DWWs. A sensitivity analysis showed no significant difference in the reduction of amounts of MOs between SAW and DWWs for either the groin (P=.97) or the perineum (P=.51).

Analysis of the species of MOs with the potential to cause HAUTIs showed that the number of MO species increased in the swab samples from 316 to 339 after washing with SAW and from 279 to 291 after washing with DWWs. However, the amounts of MOs (1, 2, or 3 on an ordinal scale) in all of the swap samples decreased after washing with SAW from 603 to 522 and from 504 to 424 after washing with DWWs (Table 3). The analysis showed a significant reduction in the amounts of MOs after washing with SAW (P=.0008) and after washing with DWW (P=.0001) for MOs with the potential to cause HAUTIs; however, there was no statistically significant difference (P=.70) in the reduction of amounts of MOs between SAW and DWWs (summarized data) (Table 3).

The number of *Escherichia coli* increased from 38 to 44 after washing with SAW and from 28 to 31 after washing with DWWs, and the amounts of MOs (1, 2, or 3 on an ordinal scale) in all of the swap samples decreased from 60 to 55 after washing with SAW and from 39 to 34 after washing with DWWs (Table 3). However, the analysis did not show a statistically significant reduction in the amounts of MOs after washing with SAW (P=.48) or after washing with DWWs

(P= .28) (Table 3). Furthermore, no statistically significant difference (P= .57) was seen in the reduction of amounts of MOs between SAW and DWW for E coli.

DISCUSSION

The paired-samples analysis showed a statistically significant reduction in the amounts of all MOs and in the amounts of MOs with the potential to cause HAUTIs after washing with both SAW and DWWs. No statistically significant reduction was found in the amounts of *E coli*. When comparing the use of SAW with the use of DWWs, no statistically significant difference was found in the reduction of amounts of all MOs, in the amounts of MOs with the potential to cause HAUTIs, or in in the amounts of *E coli*. Thus, the null hypothesis of no difference in the reduction of amounts of MOs could not be rejected. These findings are in line with other studies^{8,9,14} that also found that SAW and DWWs were similar in their ability to reduce amounts of MOs from the skin, although these results may not be directly comparable with the present study. One study was performed on infants, ¹⁴ and another study obtained skin swabs 5 days after the washing from skin sites not related to the urethral meatus.⁹

The reduction in amounts of MOs was larger in the groin compared to the reduction in the perineum, but the difference was not statistically significant. The difference could, however, be explained by the groin being easier to wash and swab compared to the perineum. A small reduction of the amounts of *E coli* after washing with either SAW or DWWs was found, but it was not statistically significant. This is an interesting result, given that *E coli* is the primary cause of the majority of HAUTIS.³ The number of *E coli* found in our study was low (50 for SAW and 33 for DWW), which may explain why the findings were not statistically significant.

Contamination with new species of MOs was observed after washing with both SAW and DWWs. This, too, is in line with other studies 8,9,14 and indicates that the transfer of MOs from the participants' own gut flora or from the environment might contaminate participants during the washing procedure. Contamination may also occur due to variations in how the skin swabs are obtained. Despite contamination with new MOs, the amounts of MOs decreased significantly after washing with both SAW and DWWs. Thus, on average, the participants became microbiologically less contaminated after washing. Both washing methods seem to meet their purpose—namely, to reduce the bioburden on patients' skin and thus potentially reduce the risk of HAUTIs.

Despite the fact that the amount of all MOs was statistically equally reduced after either washing method, the nursing staff sometimes found that it was difficult to wash the patients' visibly clean after fecal incontinence, especially when using DWWs. This is in accordance with other studies reporting that DWWs sometimes are less effective than SAW in removing dirt and feces.^{6,13} Thus, from a clinical perspective, SAW and DWWs are not necessarily equally effective.

Strengths and limitations

Even though the pilot study provided some experience of the process, it was a logistic challenge to include more than one participant per day who had an influence on the inclusion rate, apart from reasons related to the individual patients. The main reason for non-participation was the lack of ability to sign an informed consent form. Furthermore, 14 patients dropped out because of unforeseen events. There is a risk of committing a type II error because the study did not achieve the estimated power calculation.

The same person obtained all skin swabs, which contributed to minimizing collection bias; however, even though the swabbing method was standardized, the swabbed skin size, the rolling

[†]Percent of participants for whom the interventions had no effect.

[‡]Percent of participants with a reduction after the interventions.

technique, and the pressure used when swabbing may have differed. Furthermore, the moist swab may not have collected all of the MOs from the skin.¹⁷

The random variation in the number of species found for each participant made it difficult to compare the microbiological reduction between the two interventions. As patients are expected to become less contaminated overall after washing, it was considered to be clinically relevant to sum up the amounts of MOs for each participant and each intervention in the statistical analysis.

According to the Danish national guidelines,³ intimate hygiene for a patient with a diaper should be performed every 12 hours. As the skin swabbing was done at an interval of approximately 24 hours, up to 90% of the participating patients with a diaper may have been washed at least one additional time after the first washing intervention. All patients should be washed after each wet diaper.

The carryover effect in crossover studies^{20,21} depends on how rapidly MOs are re-established on the skin, the diversity in the profile of the human skin microbiota, and other individual variations.²³ Using a diaper may also have an influence on the skin microbiota and how quickly the MOs re-establish. Due to the crossover design, the impact of demographic variations on the results was reduced. Intimate hygiene can be performed in many different ways depending on the individual patient's, staff's, and environmental circumstances; however, adhering to local guidelines for the washing procedure before and during the study might have contributed to better consistency.

It is considered a strength that the majority of participants were washed by the same person on both days, as the nursing staff may have differed with regard to individual experience and routines, resulting in differences in how the washing procedures were performed. The same nursing staff washing all of the patients could lead to bias in the procedure because of staff preferences. It was not possible to blind the staff as to what washing method they used. This could also lead to bias in the washing procedure because of staff preferences; in fact, two studies concluded that nurses prefer to use DWWs. 7.8 Furthermore, the staff could have been performing the washing procedures more thoroughly because the person obtaining the swabs was observing them while they did so.

This study did not address long-term effects of using either SAW or DWWs, and it only assessed a specific brand of DWWs. Furthermore, some of the nursing staff heated the DWWs before washing, which may have had an influence on the effectiveness of the wipes.

CONCLUSION

There was no significant difference between washing with SAW or DWWs with regard to their effectiveness in reducing the amounts of MOs on the skin, indicating that both methods seem to be equally effective in removing microorganisms from the skin. There was a statistically significant reduction in the amounts of MOs after washing with either SAW or DWWs, including MOs that potentially could cause HAUTIs; however, both methods introduced contamination with new species of MOs. A small reduction in the amount of *E coli* after washing with either SAW or DWWs was observed, but it was not statistically significant.

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