A CLUSTER-RANDOMIZED CONTROLLED TRIAL OF CATHETER REMINDER AND EVALUATION (CARE) PROGRAM TO REDUCE CATHETER-DAY AND CATHETER-ASSOCIATED INFECTIONS: RESULTS FROM AGGREGATE DATA ANALYSIS

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ABSTRACT

Background: Prolonged use of urinary catheter is considered a major risk factors for catheter-related urinary tract infections (CA-UTIs). Many guidelines recommend removal of urinary catheter when appropriate indications are not present. Our study aimed to evaluate the impact of the CARE program on urinary catheter days in general medical wards.

Methods: A cluster RCT with wards as the unit of randomization was conducted during Feb 1, 2013 - April 30, 2013 at Siriraj hospital, Bangkok, Thailand. Six general medical wards were randomly allocated to either the intervention (CARE program) group or the control group. The CARE program involved two steps. First: a ward nurse evaluated each patient on daily basis. If a given patient had an acute urinary catheter in place, an order sheet then was marked with a CARE stamp indicating the first date of catheter use. Second: a responsible physician filled an indication of catheter use during a service round. If an appropriate indication was not written, a given urinary catheter then was automatically removed. Individual data was obtained by chart- review while all aggregate data were obtained via Siriraj Infection Control Surveillance System.

Results: Data of urinary catheter-days and patient-days in each group 3 months before/after starting the study are shown in figure 1. Median rate of urinary catheter use (catheter days/1,000 patient days) was comparable between the intervention group [380.0, range 232.8-443.6] and the control group [321.4, range 244.3-431.7], by unadjusted analysis (p=0.40). We also performed additional analysis by using only data from 3 intervention wards before and after starting the study. Segmented poisson regression analysis revealed a significant lower rate of urinary catheter use after the intervention implemented [RR=0.67 (0.57-0.77);p<0.001].

Conclusion: The pre/post analysis revealed the positive impact of the CARE program while no effect was detected by analysis with the parallel control. Since we used cluster randomization, baseline characteristics between 2 groups may be different. Hierarchical model adjusting for clustering effect should be performed to determine the real effect of this program.

METHODS

SETTINGS: From Feb 1, 2013 - April 30, 2013, we conducted a cluster-randomized control trial at Siriraj hospital, a 2200-bed, tertiary-care university hospital in Bangkok, Thailand. Six general medical wards were randomly allocated to either the intervention (CARE program) group or the control group. The study was approved by Siriraj Institutional Review board.

INTERVENTION: The CARE program consists of two steps. First: a ward nurse evaluated each patient on daily basis. If a given patient had an acute urinary catheter in place, an order sheet then was marked with a CARE stamp indicating the first date of catheter use. Second: a responsible physician filled an indication of catheter use during a service round. If an appropriate indication was not written, a given urinary catheter then was automatically removed.

DATA COLLECTION: Individual data including baseline characteristics, duration of hospitalization, duration and indication of urinary catheter use, presence of catheter-associated infection and clinical outcomes was obtained by chart-reviewing. Aggregate data including catheter day an patient day during the study period as well as 3 months prior the study period was obtained via Siriraj Infection Control Surveillance System.

Figure 1. Data of urinary catheter-days and patient-days in each group 3 months before/after starting the study

■ Urinary catheter day, CARE ▢ Paitent day, CARE ■ Urinary catheter day, Control ▢ Patient day, Control
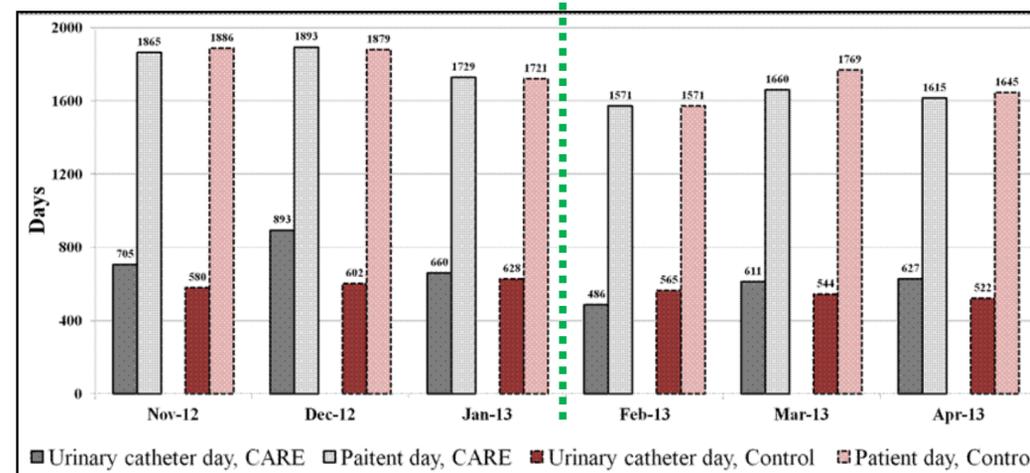
STATISTICAL ANALYSIS:

Categorical variables were summarized by frequency while continuous variables were summarized by the mean, median, standard deviation, and range as appropriate. Segmented poisson analysis was performed to evaluate the effect of intervention overtime. For all calculations, a two-tailed P value of <0.05 was considered statistically significant. All calculations were performed using the STATA version 12.0 (Stata Corp, College Station TX).

RESULTS

The total urinary catheter-day and total patient-day in the CARE group and the control group in each month are shown in the figure 1. Median of urinary catheter-day and rate of urinary catheter use (catheter-day per patient-day) in the CARE group and the control group across the calendar month are shown in table 1.

Table 1. Urinary catheter-day and rate of urinary catheter use (catheter-day per patient-day) among the CARE vs. control group , by the calendar month.

PERIOD	Urinary Catheter-day		Rate of Urinary Catheter Use	
	CARE	Control	CARE	Control
Nov 2012	223 (192-290)	227 (188-288)	0.34 (0.32-0.45)	0.35 (0.29-0.44)
Dec 2012	282 (206-405)	220 (216-258)	0.42 (0.34-0.64)	0.33 (0.33-0.40)
Jan 2013	236 (182-242)	227 (154-256)	0.40 (0.32-0.40)	0.38 (0.25-0.43)
Before period (Nov 12-Jan 13)	236(182-405)	227 (154-288)	0.40 (0.33-0.65)	0.36 (0.26-0.45)
Feb 2013	140 (122-224)	179 (172-184)	0.26 (0.23-0.43)	0.35 (0.33-0.35)
Mar 2013	213 (181-217)	185 (180-203)	0.35 (0.31-0.36)	0.32 (0.31-0.35)
May 2013	217 (169-243)	186 (139-205)	0.39 (0.32-0.44)	0.33 (0.26-0.38)
After period (Feb -April 13)	213 (122-243)	184 (139-205)	0.36 (0.23-0.44)	0.34 (0.27-0.38)

Comparison of CARE group vs. Control group [Feb –Apr 2013]:
During the 3-month of study period, the median number of catheter-day was 213 [122-243] in the CARE group and 184 [139-205] in the control group. There was no significant difference between two group (univariate p=0.34). Median rate of urinary catheter use was comparable between the CARE group (0.36 [0.23-0.44]) and the control group (0.34[0.27-0.38]) by unadjusted analysis (p=0.30).

Comparison of Before vs. After period (data from three intervention wards)
We also performed additional analysis by using only data from 3 intervention wards before and after initiation of the CARE program. Median rate of urinary catheter use was 0.40 (0.33-0.65) during the before period and then dropped to 0.36 (0.23-0.44) during the after period. There was no difference between the before and after period by univariate analysis (p=0.20). However, the segmented poisson analysis revealed a significantly lower rate of urinary catheter use after the intervention implemented [RR=0.67 (0.57-0.77);p<0.001].

Table 2. Segmented poisson analysis of data from 3 intervention wards

Segmented poisson analysis	Relative Risk [95% CI]	P-value
Baseline trend	1.01 [0.961-1.06]	0.08
Level change after the intervention	0.67 [0.57-0.77]	<0.001
Trend change after the intervention	1.11 [1.02-1.20]	0.008

CONCLUSION:

Our cluster RCT did not revealed the positive impact of CARE program when using the aggregate data. Since we used cluster randomization, baseline characteristics between the control wards and the intervention wards may be different. Hierarchical model adjusting for clustering effect should be performed to determine the real effect of this program.

However, the pre/post analysis revealed the positive impact of the CARE program on reducing the rate of urinary catheter use (RR=0.67 [0.57-0.77]). To be noted, this positive impact did not sustain and the rate of urinary catheter use later increased overtime (RR= 1.11 [1.02-1.20]). Therefore, future studies seeking for the development of sustainability for infection control interventions are still in need.