“Swallowing and nutritional complications after endotracheal extubation: A study covers both whether and how”

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National Science Council of Taiwan: 08/01/2012-07/31/2015

Swallowing and nutritional complications after endotracheal extubation occurred commonly and affected patients across all diagnostic categories, particularly for patients older than 50 years. Because oral intake is an important component of patient recovery after critical illness, the aim of this study is to develop and evaluate an oral cognitive care protocol for the reduction of swallowing and nutritional complications in older patients after prolonged endotrachel intubation. In keeping with previous research, we defined prolonged endotrachel intubation as 48 hours and longer.

Phase I: Given the dearth of data on these outcomes of interest, a prospective observational study will be conducted to assess the incidence and risk factors of swallowing and nutritional complications among patients aged 50 years and older following endotracheal extubation. Swallowing complications will be assessed at four points in time, 48 hours within extubation (T0), 7 days (T1), 14 days (T2), and 21 days (T3) postextubation. Fiberoptic Endoscopic Evaluation of Swallowing (FEES), Repetitive Saliva Swallowing Test (RSST), Sub-mental Ultrasonography (SUG), 3 steps Swallowing Screen (3-SSS), and Swallowing Questionnaire (SQ) will be used at different time points to better assess swallowing complications. Based on power analysis, 140 participants will be enrolled. Findings will add to develop an evidence-based oral cognitive care protocol.

Phase II: A prospective, single-blind, one-center randomized controlled trial (RCT) using a computer generalized randomization list will be conducted to test the effects of this newly developed oral cognitive care protocol in reducing swallowing complications (measured by FEES, RSST, SUG, 3-SSS, & SQ), improving oral health (measured by oral assessment guide, and general oral health assessment), and promoting nutritional status (measured by oral intake level, mini-nutritional assessment, and weight changes) in patients intubated for more than 48 hours. Blinded raters will assess patients 21 days following endotracheal extubation at 4 points in time (T0-T3). Patients$\geqq$50 years who had intubated$\geqq$48 hours, excluding patients with neurological and structural deficits, will be recruited consecutively from 3 intensive medical care units at NTU hospital. Based on power analysis, a sample size of 138 is sufficient to reach 80% power of analysis. Simple random assignment to the

experimental and usual care group will be performed. Strict adherence to the resulting randomization will be ensured.

The intervention consisted of a daily oral cognitive care protocol on two core components, oral care (cleaning and oral function stimulation) and cognitive stimulation. Usual care consisted of standard hospital services and the same physicians provide care to patients in both experimental and usual care groups.

Data will be analyzed using the SAS package. The intention-to-treat principle will be used. Generalized Estimating Equation will be performed to test the intervention effect. This study will cover not only “whether” but “how” to intercede postextubation swallowing and nutritional complications. It is also the first RCT study to test the effect of oral cognitive care in reducing swallowing and nutritional complications in older patients after endotracheal extubation.