“Screen and intervene: a diagnostic accuracy study and a randomized controlled trial for postextubation dysphagia”
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Endotracheal intubation is life-sustaining, but it may contribute to postextubation dysphagia (PED) increasing the risk of penetration, aspiration, and aspiration pneumonia. Up to 84% of postextubated patients had PED and approximately 60% penetrated and aspirated that can lead to aspiration pneumonia. The aims of this three-year, two-stage study are: 1) to develop a two-step PED Screen involved oral stereognosis and cough reflex test for detecting penetration and aspiration, using a diagnostic accuracy study method; and 2) to test effects of a once daily, 7-day PED Care intervention on reducing time to resume oral intake, rates of penetration and intervention at 10 days postextubation, and incidences of 30-day aspiration pneumonia in adult patients with prolonged intubation (≥48 hours) from a medical center in Taiwan, using a randomized controlled trial (RCT) design.

Study participants will be recruited from consecutive adult patients (≥ 20 years) who had been admitted to the medical center’s 6 medical intensive care units and received emergency oral endotracheal intubation for at least 48 hours. Upon receiving informed consent, all participants will receive a PED Screen involving the tests of oral stereognosis and cough reflex administrated by two trained research nurses to establish the inter-rater reliability of PED Screen. Within 30-minute of completing PED Screen, a Fiberoptic Endoscopic Evaluation (FEES) as a gold-standard to identify penetration and aspiration will be conducted by a blinded ear, nose, and throat(ENT) physician (Co-P.I.) to establish sensitivity and specificity. Whether the optimal cutoff points will be differed between younger (20-64 years) and older (≥ 65 years) patient groups will be examined.

Regardless of participants’ test results, all participants will then be randomized into the experimental and usual care groups. In addition to usual care, the experimental group will receive the once daily, 7-day intervention program (PED Care) provided by a trained intervention nurse. The PED Care will consist of two nurse-administered protocols targeting muscular lingual weakness and slow neural responses for patients with prolonged intubation. The primary outcomes will include time to resume oral intake, rates of penetration and intervention at 10 days postextubation (coded by

FEES), and incidences of 30-day aspiration pneumonia. All outcomes will be assessed by two trained research nurses who are blinded to the group assignment.

The first stage of PED Screen study will follow the guidance of Standards for Reporting Diagnostic accuracy studies (STARD) and the second stage of PED Care study will follow the Consolidated Standards of Reporting Trials (CONSORT) Statement. Based on power analysis, 172 participants will be enrolled and followed for 30 days postextubation. This will be the first study to develop a brief, 10-minute postextubation dysphagia screening for patients with prolonged intubation. This will also be the first RCT to test the effects of a nursing intervention on reducing time to resume oral intake, rates of penetration and intervention at 10 days postextubation, and incidences of 30-day aspiration pneumonia in adult patients with prolonged intubation.

Keywords: postextubation dysphagia; endotracheal intubation; dysphagia screening, dysphagia intervention; randomized controlled trial