Official Titled：Assessment of Functionality and Performance of a Novel Tracheostomy Tie

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Background

Tracheotomy is a common procedure for multiple medical indications.Tracheostomy tubes must be securely fixed to prevent movement or decannulation and tracheostomy ties must be exchanged as needed. However, the process of ties exchange is always risky and complicated. A novel tracheostomy tie has been designed to ensure the safety during exchanging and conveniences of cleaning.

Objective: To evaluate if the novel tracheostomy ties promotes and facilitates the safe care of tracheostomies.

Design and Methods: This is a 2 arms open label randomized phase 2 study. Sixty tracheotomy patients without an existing neck injury will be recruited. Patients in experimental group wear a novel designed tracheostomy tie, the primary feature of which is double belts to ensure the safety during exchanging and conveniences of cleaning. The traditional one was used in control group.

Inclusion criteria include: 1. Subjects ≥ 18 years old and ≤ 60 years old; 2. Patients with a tracheostomy; 3. With intact neck skin; 4. Willingly signs the Informed Consent; 5. Is qualified to participate in the opinion of the Investigator; 6. Without disorders of consciousness. Exclusion criteria include: 1. With an existing neck injury or infection or clinically significant skin diseases on the application site which may contraindicate participation, including psoriasis, eczema, atopic dermatitis, active cancer; 2. With damaged skin or conditions on the application site which includes sunburn, scars, moles or other disfiguration of the test site; 3. Has a known or stated allergy to adhesive bandages, or any of the product types being tested. 4. Uses of topical drugs on the application site; 5. Uses lotions, creams or oils on the application site; 6. Can not communicate with nurses or doctors for any reasons

Outcome measures

Primary Outcome Measure:

1.Subjective index: Difficulty level of exchanging or cleaning the tracheostomy ties. Nurses will be evaluated by Visual Analogue Scale/Score to measure the difficulty level of exchanging or

cleaning the tracheostomy ties.

2.Objective index: local skin breakdown. Scale for surrounding skin breakdown of tracheotomy wound was rated as mild, moderate, or severe. “Mild” wounds included fragile skin that was erythematous or had a small amount of breakdown (<1 cm in diameter). Wounds with evident skin erosion or breakdown associated with drainage and/or pain were classified as “moderate.” “Severe” wounds were defined as a partial-thickness loss of dermis presenting as a shallow open ulcer with a red-pink wound bed.

Secondary Outcome Measure:

3. Subjective index:degree of comfort during wearing or exchanging tracheostomy ties. Visual Analogue Scale/Score will be used to measure the degree of comfort of patients during wearing or exchanging tracheostomy ties

4. Objective index:the actually frequency of exchanging dressing. The record of the frequency of exchanging dressing under the tracheostomy ties in practice will be collected.

Statistical analysis plan:

The hypothesis of this phase II study is that the use of the novel tracheostomy tie will be more comfort and easier to manipulate than traditional one without compromise to safety.

The data will be collected 14 days after tracheostomy. The wound breakdown and the actually frequency of exchanging dressing will be evaluated and recorded by nurse in charge. The visual analogue scale/score of outcome measurements will be administered to the patients and nurses respectively.

Visual Analogue Scale/Score of difficulty level of exchanging or cleaning the tracheostomy ties, degree of comfort during wearing or exchanging tracheostomy ties and the actually frequency of exchanging dressing between the experimental group and control group will be compared using independent sample T-test. Data analysis of the rate of skin breakdown will performed using Fisher’s exact test. Statistical analysis will be performed with the SPSS software version 17.0. Significance will be set at $P<0.05$.

This study is planned to last for 1-2 years.