

Randomized Trial for Comparison of Tracheostomy Tie Outcomes: Conventional by Cotton Tape and Innovative by Suction Tube

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Objective: To compare the outcomes of using a tracheostomy tie between a traditional cotton tape tracheostomy tie, and an innovative model, applied from a suction tube.

Materials and Methods: One hundred sixty-four patients that underwent tracheostomy tube replacement between June 2022 and March 2023 at Sawanpracharak Hospital, Nakhonsawan Province, were analyzed by the ENT group. Eighty-two cases were randomly divided into groups using traditional tracheostomy ties of cotton tape and 82 cases using an innovative suction tube as a tracheostomy tie. The general data of the patients were evaluated using descriptive statistics. For comparison of differences between the two groups of data, categorical data was analyzed by chi-square and continuous data was analyzed by independent t-test and VAS score was analyzed by Mann-Whitney test. A p-value of less than 0.05 was considered as a statistically significant difference.

Results: The result of the study showed that age and gender did not have statistically significant differences in both groups of patients. In the group that received the tracheostomy tie, the tracheostomy tube displacement was more frequent, and there was more dirt and moisture around the tracheostomy tie than in the group that received an innovative tracheostomy tie with a suction tube. This was statistically significant. Patients and caring nurses were statistically significantly more satisfied using the innovative tracheostomy tie made by a suction tube.

Conclusion: A suction tube is an ideal alternative material for personal care, reducing superficial injury of the skin and reducing the risk of accidental decannulation. The tracheostomy tie made of a suction tube is considered an alternative use.

Keywords: Tracheostomy tie; Tracheostomy tube; Suction tube; Cotton tape

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The tracheostomy is usually performed in patients with prolonged mechanical ventilation, maintaining a secure airway when the upper airway is unsafe such as in head neck injuries, neurogenic compromise, maintaining pulmonary toilet, or upper airway obstruction^(1,2). While using a tracheostomy tube, a tracheostomy tie is typically made of cotton tape firmly fixed around the patient's neck and not removed until the time of changing the tracheostomy tube. If the tracheostomy tie was too loose, the tube may slip out of its original position. This problem can

be life-threatening. It was also noted that the cotton tie became dirty and wet when in contact with mucus and water, and the cotton tie became stiff, causing ulcers of the skin around the neck. According to the literature review, 1% to 6.7% of tracheostomy tubes were dislodged^(3,4) and 20% to 44% found superficial skin injury around the neck⁽³⁻⁵⁾ in patients using the tracheostomy tie by cotton tape. Because of these problems, a tracheostomy tie was developed to make it easier for patients and their families to reduce the occurrence of superficial skin injuries from cotton ties and to reduce contamination by contact with water or sputum. A size No. 10 suction tube is used as a tracheostomy tie. It has an appropriate length around the neck and the diameter is just right to be inserted into the hole at the tracheostomy flange without being too loose or too tight. The components of the tracheostomy tube are shown in Figure 1.

The purpose of the present study was to compare the outcomes between using a traditional cotton tape tracheostomy tie, and an innovative model, applied from a suction tube. The results of the present study

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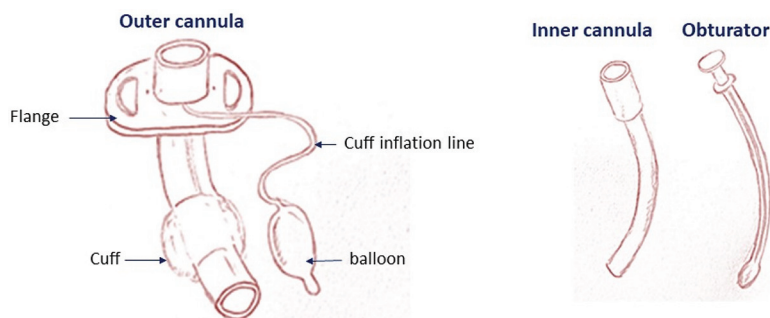


Figure 1. Installation of tracheostomy part.

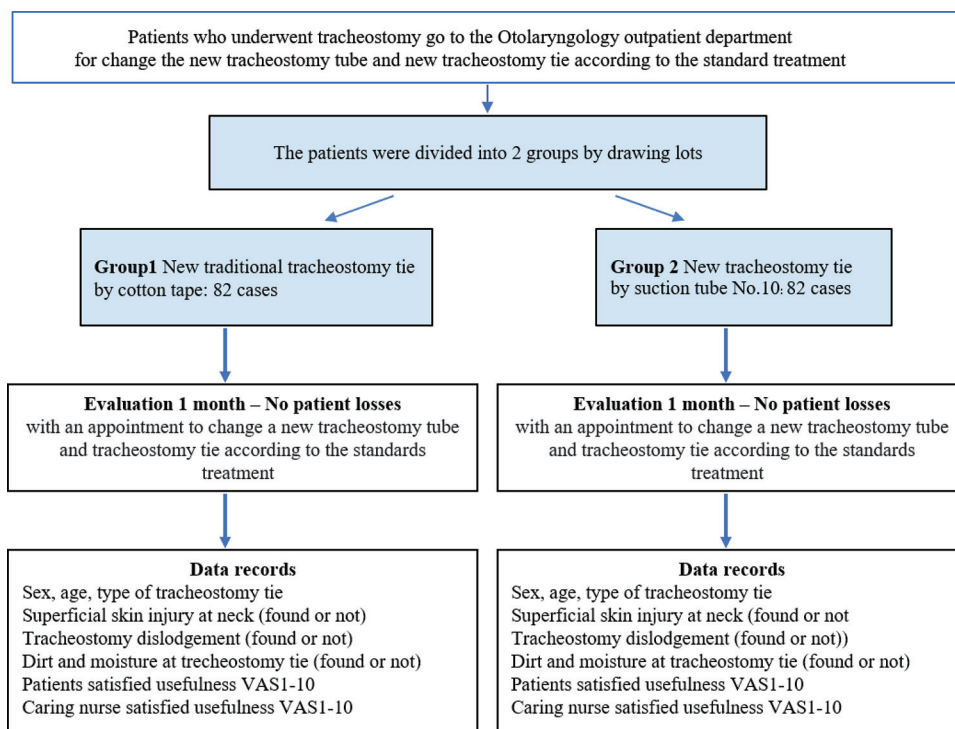


Figure 2. Installation method of conducting research.

were applied as a guide for selecting an effective tracheostomy tie. The current study had not been done before.

Materials and Methods

The present study was a randomized trial study conducted at Sawanpracharak Hospital between June 2022 and March 2023. Inclusion criteria were patients over 18 years old that undergone tracheostomy and went to the Otolaryngology Outpatient Department for a change of tracheostomy tube as a standard treatment. Exclusion criteria were 1) patients with intellectual disabilities unable to take care of the tracheostomy tube by themselves

and did not have relatives, and 2) patients unable to communicate with their doctor. The present study was approved by the Human Research Ethics Committee of Sawanpracharak Hospital No. 12/2565. The Thai clinical trials registry was done, TCTR ID: TCTR20230228007. The method of conducting research is shown in Figure 2. One hundred sixty-four patients who underwent tracheostomy tube replacement between June 2022 and March 2023 were analyzed by the ENT group. The patients were divided into two groups by drawing lots, with 82 cases using traditional tracheostomy ties of cotton tape and 82 cases using an innovative suction tube No. 10 as a tracheostomy tie. Both types of tracheostomy tie are

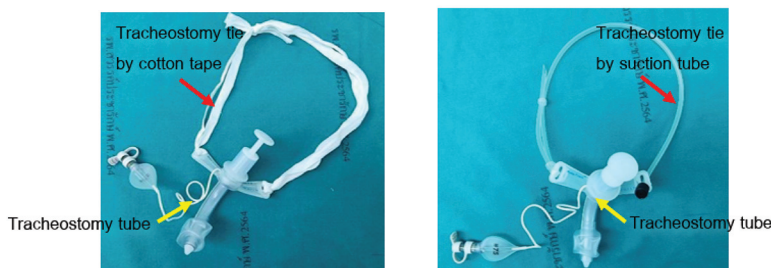


Figure 3. Shows the conventional tracheostomy tie by cotton tape and innovation by suction tube No. 10.

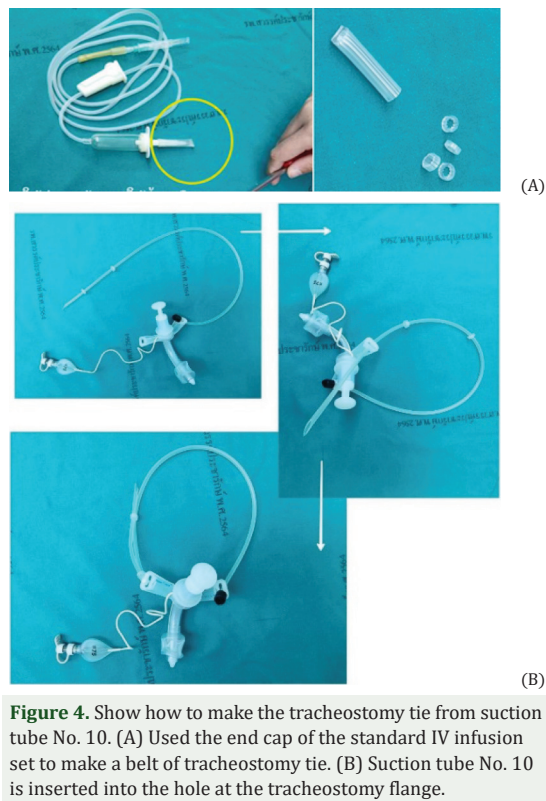


Figure 4. Show how to make the tracheostomy tie from suction tube No. 10. (A) Used the end cap of the standard IV infusion set to make a belt of tracheostomy tie. (B) Suction tube No. 10 is inserted into the hole at the tracheostomy flange.

shown in Figure 3. Figure 4 shows how to make the tracheostomy tie from a suction tube No. 10.

One month later, a follow up appointment for treatment and replacement of the new tracheostomy tube and tracheostomy tie according to the standard treatment^(1,2,6) was done. The primary outcome was the presence of superficial skin injury of the neck under the tracheostomy tie. The secondary outcomes were dirt and moisture at the tracheostomy tie, history of tracheostomy tube dislodgement, and visual analog scale (VAS) score by patients and caring nurses. The data were collected by reviewing outpatient medical records with information on gender, age, and history of tracheostomy tube dislodge. The dirt and moisture

around the tracheostomy tie and superficial skin injury on the neck were evaluated by the doctor. The VAS scores of satisfied usefulness were evaluated by patients and caring nurses.

Statistical analysis

From the literature review⁽³⁾, to study the difference in complications between twill or same cotton tie, and Velcro tie, revealed that 44% of skin-related complications were in the twill group and 23% in the Velcro group. The sample size for comparing two population proportions was calculated by

$$n_1 = \left[\frac{z_{1-\frac{\alpha}{2}} \sqrt{\bar{p}\bar{q} \left(1 + \frac{1}{r}\right)} + z_{1-\beta} \sqrt{p_1q_1 + \frac{p_2q_2}{r}}}{\Delta} \right]^2$$

$$\Delta = p_1 - p_2, \quad \bar{p} = \frac{p_1 + p_2r}{1+r}, \quad r = \frac{n_2}{n_1}$$

$$q_1 = 1 - p_1, \quad q_2 = 1 - p_2, \quad \bar{q} = 1 - \bar{p}$$

Substitute in the formula with proportion of group 1 (P1)=0.44, proportion of group 2 (P2)=0.23, Alpha type I error=0.05, Z(0.975)=1.96, Beta type II error=0.20, Z (0.800)=0.84, r=1, $\Delta=p_1$ and p_2 difference. Therefore, the sample size $N_1=82$, $N_2=82$, and the total sample size in both groups were 164.

The quantitative data were evaluated using descriptive statistics such as percentage, mean, and standard deviation. The comparison of differences between the two groups of data, categorical data was analyzed by chi-square, continuous data was analyzed by independent t-test, and VAS score was analyzed by Mann-Whitney test, where a p-value of less than 0.05 was considered as statistically significant difference. Statistical analyses were performed using IBM SPSS Statistics, version 26.0 (IBM Corp., Armonk, NY, USA).

Results

One hundred sixty-four patients that undergone tracheostomy tube replacement between June 2022 and March 2023 were randomized into two groups.



Figure 5. Shows the patient who used the tracheostomy tie by cotton tape with superficial skin injury (A) and suction tube No. 10 with no skin injury (B).

Eighty-two patients had a tracheostomy tied by cotton tape and included 55 males and 27 females, with a mean age of 57.29 ± 18.5 years. The other eighty-two patients used a tracheostomy tie by suction tube No. 10 and included 53 males, and 29 females with a mean age of 55.71 ± 22.89 years, as shown in Table 1.

One month after insertion of the tracheostomy tube, no patient was lost to follow-up in both groups. The tracheostomy tube and tracheostomy tie were replaced according to the standard of treatment and the patients received a physical examination. The satisfaction was scored using VAS by nurses and patients and a review of the history in the medical record was done. It was found that in the group that received the tracheostomy tie by cotton tape, nine cases had wounds on the skin under the cotton tape (Figure 5A), 14 cases had tube displacement, and 66 cases had dirt and moisture on the tracheostomy tie. In the group that received tracheostomy tie by suction tube No. 10, there were no superficial skin injuries under the suction tube (Figure 5B), no tracheostomy tube displacement, and no dirt and moisture found

Table 1. General data

Type of tracheostomy tie	Cotton tape (n=82)	Suction tube (n=82)	p-value
Sex; n (%)			0.742
Male	55 (67.1)	53 (64.6)	
Female	27 (32.9)	29 (35.4)	
Age (years); mean \pm SD	57.29 ± 18.5	55.71 ± 22.89	0.626

SD=standard deviation

The chi-square test and independent t-test

Table 2. Results after using tracheostomy tie 1 month

Type of tracheostomy tie	Cotton tape (n=82) n (%)	Suction tube (n=82) n (%)	p-value
Superficial skin injury at neck			0.002*
Found	9 (11.0)	0 (0.0)	
Not found	73 (89.0)	82 (100)	
Tracheostomy tube displacement			<0.001*
Found	14 (17.1)	0 (0.0)	
Not found	68 (82.9)	82 (100)	
Dirt and moisture			<0.001*
Found	66 (80.5)	0 (0.0)	
Not found	16 (19.5)	82 (100)	

* $p < 0.05$, chi-square test

Table 3. Satisfaction survey using VAS score

	Cotton tape (n=82) median (IQR)	Suction tube (n=82) median (IQR)	p-value
Patients satisfied usefulness VAS1-10	5.5 (4, 8)	10 (10, 10)	<0.001*
Caring nurse satisfied usefulness VAS1-10	4.5 (3, 7)	10 (10, 10)	<0.001*

IQR=interquartile range

* $p < 0.05$, Mann-Whitney test

as shown in Table 2.

When surveyed for satisfaction using VAS scores, one was dissatisfied, five were moderate and ten were most satisfied. It was found that patients were satisfied with the tracheostomy tie by cotton tape with a median score of 5.5 and the tracheostomy tie by suction tube with a median score of 10. The caring nurses were satisfied with the tracheostomy tie by cotton tape with a median score of 4.5 and the tracheostomy tie by suction tube with a median score of 10, as shown in Table 3.

Discussion

The present study showed that male and female patients were equally distributed in both groups.

There was no statistically significant difference between the two groups. The average age of patients in the group with tracheostomy tie by cotton tape was 57.29 ± 18.5 years, while the average age in the group with innovative tracheostomy tie by suction tube was 55.71 ± 22.89 years. There was no statistically significant difference between the groups.

When the tracheostomy tie with cotton tape is exposed to mucus or water, the cotton tape becomes stiff, and the skin of the neck is injured. According to the literature review⁽³⁻⁵⁾, it was found that superficial injury to the skin around the neck caused by the cotton tape occurred in about 20% to 44% of the cases. In the present study, superficial injury to the skin around the neck caused by the cotton tape occurred in nine cases or 11%, and no cases were found in the group that received the tracheostomy tie by suction tube No. 10. When comparing the data from both groups, a statistically significant difference was found with a p-value of 0.002. The suction tube No. 10 is made of soft medical-grade PVC plastic. Its outer surface is smooth and uniform and does not irritate the skin. It is designed to resist temperature fluctuations and decomposition due to chemical reactions with substances⁽⁷⁻⁹⁾. It has suitable flexibility and material stability, which prevents skin injury when used for an appropriate time.

If the tracheostomy tube displaces from its original position when the patient moves, this may increase the risks of oxygen deprivation or ineffective breathing. In the review of incidents at Sawanpracharak Hospital in 2019 and 2020, it was found that of 238 patients with tracheostomy tubes, the tracheostomy tubes had slipped out of their original position in nine cases (3.7%). According to the literature review^(3,4), tracheostomy tube displacement in patients using cotton ties was found to occur in 1% to 6.7% of cases. In the present study, tracheostomy tube displacement occurred in 14 cases (17.1%) in patients using tracheostomy tied by cotton tape. No tracheostomy tube displacement was noted in the group receiving tracheostomy tied by a size ten suction tube. When comparing the data from both groups, a statistically significant difference was found with a p-value less than 0.001. The size ten suction tube is made of soft medical-grade PVC plastic designed to be resistant to temperature changes and degradation from chemical reactions or cleaning solutions⁽⁷⁻⁹⁾. This allows it to maintain its position when used as a tracheostomy tie. In addition, the securing strap can be easily adjusted like a belt so that relatives and patients can care of the tube themselves

at home and adjust it to the proper tightness.

Another problem with using the tracheostomy tie by cotton tape is the moisture problem when wet. This can lead to stains and dirt on the fabric, make it uncomfortable, esthetical unappealing to use, and promote contamination with pathogens. In the present study, the problem of wet and stained cotton tape occurred in 66 cases (80.5%) of the patients that received the tracheostomy tie by cotton tape. In contrast, the group that received a size ten suction tube had no problems with moisture and staining when wet. They were easily wiped off without leaving any residue. When comparing the data from both groups, a statistically significant difference was found with a p-value less than 0.001. The size ten suction tube undergoes a process that ensures it is pathogens-free by using ethylene oxide gas. It does not absorb moisture in contact with water, making it easy to clean without leaving stains or dirt on the material's surface⁽⁷⁻⁹⁾.

Patients' satisfaction with the convenience of use was assessed using a visual analogue scale from 1 to 10, with 1 representing dissatisfaction, 5 representing moderate satisfaction, and 10 representing highest satisfaction. It was found that patients in the group that received the tracheostomy tie by cotton tape reported a median score level of 5.5 regarding the convenience of use. In contrast, the group that received the tracheostomy tie by a size ten suction tube reported a median score level of 10 regarding the convenience of use. When comparing the data from both groups, a statistically significant difference was found with a p-value less than 0.001. This is because the suction tube is easy to clean when contaminated with mucus, and when the tracheostomy tube needs to be adjusted, caregivers can easily move and adjust it, like putting on a belt, without worrying about slipping.

The caring nurses' satisfaction with the convenience of use was assessed by a visual analogue scale of 1 to 10, with 1 representing dissatisfaction, 5 representing moderate satisfaction, and 10 representing highest satisfaction. It was found that, the caring nurses that changed the tracheostomy tube gave a median score level of 4.5 in terms of ease of use in the group that tied the tracheostomy tie by cotton tape. In contrast, in the group that used the tracheostomy tie with a size ten suction tube, the caring nurses gave median score level of 10 regarding ease of use. When comparing data from both groups, a statistically significant difference was found with a p-value less than 0.001. The caring nurses found

that changing the tracheostomy tube was easy, fast, and not complicated. They were also satisfied when observed that patients were well cared for in terms of cleanliness.

Conclusion

A suction tube is an ideal alternative material for personal care, reducing superficial injury of the skin and reducing the risk of accidental decannulation. The tracheostomy tie made of a suction tube is considered an alternative use.

What is already known on this topic?

Tracheostomy tie can be made from various materials but there is no previous study about the proper material for tracheostomy tie.

What does this study add?

This study showed that the use of a tracheostomy tie by suction tube No. 10 can reduce the complications or morbidity caused by the traditional cotton tape. It is considered to be an alternative material for the use of tracheostomy tie.

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Conflicts of interest

The authors declare no conflict of interest.

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