A tracheostomy shared decision making program in respiratory care center patients in Taiwan

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Abstract

Background: Tracheostomy is recommended for respiratory care center prolonged mechanical ventilation patients who cannot be liberated from the ventilator in the short term. However, most patients or their families oppose having this procedure. We applied [If my family is difficulty liberated from the ventilator, do he/she need to undergo tracheostomy?] tracheostomy shared decision making program for respiratory care center prolonged mechanical ventilation patients. The program is expected to enable patients to undergo tracheostomy, improving patients’ medical care and outcomes.

Methods: We apply tracheostomy shared decision making program to patients who were admitted to a respiratory care center. Data of patients in the respiratory care center who participated in tracheostomy shared decision making program were collected and analyzed. The survival of patients and the optimal decision marking of tracheostomy shared decision making program were tracked.

Results: A total of 57 patients participated in tracheostomy shared decision making program. Of these, 39 patients (68.4%) were men, and 18 (31.6%) were women. The mean age was 69.6 years. At the end of the study, 37 patients underwent tracheostomy (64.9%), and 20 patients maintained endotracheal tube intubation (35.1%). There was no significant difference in the factors of concern and the degree of concern about the methods of treatment in the two group patients. Patients or their families of the two groups have a good understanding of the two methods of treatment. The survival rate of patients undergoing tracheostomy was 86.5%, but only 86.5% of participants believed that they made an optimal decision based on the result of the tracheostomy shared decision making program. Conversely, the survival rate of patients who maintained endotracheal tube intubation was 40%, but the all of participants believed that they made an optimal decision based on the result of the tracheostomy shared decision making program. The overall 91.2% of participants made an optimal decision marking of the tracheostomy shared decision making program.

Conclusions: The clinical application of tracheostomy shared decision making program has achieved excellent results. Patients who underwent tracheostomy will have a longer survival time.

Introduction:
Medical Shared decision making (SDM) involving the staff and patient was proposed in the United States in 1982 to promote patient care and to improve the mutual respect and communication between medical staff and patients [1]. This SDM between medical staff and the patient, which has implemented for a long time, is regarded as the ideal model for clinical treatment decision making. Advocating that patients participate in medical decision making not only helps patients understand their disease and the treatment options, but also increases patient satisfaction with medical services, increases patient safety, improves the quality of the medical treatment received and promotes medical care. In Taiwan, the Ministry of Health and Welfare introduced the medical staff and patient SDM model in 2016. SDM is designed to help patients understand disease information and the options involved in the treatment methods available. Based on the evidence, the medical team conducts disease analysis and allows medical staff and patients to propose different treatment methods before making therapeutic decisions. After discussion, patient feedback factors they cared about and the degree to which they cared about each. Then, patient decides the best option among all feasible treatments. Expect to achieve the goal of two-way communication.

“The Trial Plan for National Public Health Insurance Ventilator Dependent Patients Comprehensive Care System” has been promoted in Taiwan since 2000 [2]. The system involves four phases of care (intensive care unit, ICU; respiratory care center, RCC; respiratory care ward, RCW; and home care) for patients on prolonged mechanical ventilation (PMV). The RCC is a subacute stage for patients undergo ventilator support for more than 21 days. The goal of RCC care is to aggressively wean PMV patients off the ventilator. Some of these patients are indicated to undergo tracheostomy. Tracheostomy is recommended for RCC patients who cannot be liberated from the ventilator in the short term. However, most patients or their families oppose having this procedure. The most common reasons for refusal are that the operation will leave a wound in the patient's neck; worry about the risks and complications of the tracheostomy; worry that the patient's wound will not heal; and subjectively incorrect views of the family. These incorrect views include: 1) tracheostomy will prolong the patient's disease course and increase the burden on the family; 2) tracheostomy will increase the patient's pain and shorten the patient's life; and 3) after the tracheostomy, the tracheostomy tube
can never be removed, and the patient must remain in bed for a lifetime. Therefore, many families believe that it is better to let the patient suffer from the side effects and discomfort of endotracheal tube intubation rather than to permit tracheostomy.

Methods:
Tracheostomy shared decision making program:
Dalin Tzu Chi Hospital began [If my family is difficulty liberated from the ventilator, do he/she need to undergo tracheostomy?] tracheostomy shared decision making program in 2017. The program is expected to enable patients in the RCC to undergo tracheostomy, improving patients’ medical care and outcomes. This article shares the preliminary results of the tracheostomy SDM program of the RCC patients in our hospital.

Subject selection:
We set up a [If my family is difficulty liberated from the ventilator, do he/she need to undergo tracheostomy?] tracheostomy SDM program (appendix). A retrospective design was used to collect all data from those who participated in the tracheostomy SDM program from December 2017 to December 2018. Included were patients incapable of being removed from the endotracheal tube with the ventilator, patients with intubation and inability to cough appropriately, and patients with upper airway obstruction.

Ethics:
The study conformed to the Declaration of Helsinki 1975, revised Hong Kong 1989. The project was approved by the Buddhist Dalin Tzu Chi general hospital research ethics committee (Approved IRB No.: B10802009). All participants (patients and their family members) provided written informed consent to participate.

Program steps:
The tracheostomy SDM program included four steps. In step one, patients and their families were invited to compare the advantages, risks, side effects, complications, costs, and alternatives of each option. In step 2, when they chose a treatment, participants were asked about the factors they cared about and the degree to which they cared about each. In step 3, we tested the knowledgeability of
the patient or family about the treatment. In step 4, we asked the patient or family to confirm their decision about the treatment method. After patients transferred out of the RCC, we tracked the survival of each by telephone in January 2020 and confirmed the satisfaction of the patient or the patient's family with the use of the tracheostomy SDM program.

Statistical analysis:
Continuous variables are expressed as mean ± SD or median (range), whereas categorical variables expressed as frequencies and percentage. Differences in baseline characteristics and causes of respiratory failure were evaluated using the Student's t-test for continuous variables and Pearson chi-square tests for categorical variables. Step 2, step 3, the survival of patients, the successfully weaned patients, and satisfaction of the patients or the patients' family with the use of the tracheostomy SDM program were evaluated using univariable logistic-regression analyses. All statistical analyses were conducted using the statistical package SPSS for Windows (Version 17.0, SPSS Inc., Chicago, IL) and a P value <0.05 was considered to show statistical significance.

Results:
Fifty-seven RCC patients attended the tracheostomy SDM program during this period. The clinical data of the patients are listed in Table 1. The average age of patients was 69.6 years; 68.4% were men, and 31.6% were women. The primary cause of respiratory failure in patients was pneumonia (40.3%).

The results for the questions about treatment are provided in Table 2. Patients chose tracheostomy primarily for the following reasons, in order of importance: a) comfort of the patient, b) patient can eat or speak, c) patient can discharge and return home. The primary reasons for choosing to maintain endotracheal tube intubation, in order of importance, were: a) comfort of the patient b) patient can eat or speak, c) complications of a tracheostomy. The differences in response between the two groups of patients was not statistically significant.

The results of the test of patient or family knowledge are shown in Table 3. The most missed topics, in order, were 1) tracheostomy will prolong the patient's disease course and increase the burden on the family; 2) after tracheostomy, the patient will be liberated from the ventilator; and 3) after
tracheostomy, the incidence of pneumonia and mortality will reduce. The differences in correct answers between the two groups of patients was not statistically significant.

Of the 32 patients who initially decided to undergo a tracheostomy, three patients later decided to maintain endotracheal tube intubation. Twenty-two patients chose to keep the endotracheal tube intubation, but six patients later changed their mind to undergo a tracheostomy. Three patients had to discuss with other relatives and friends before making a decision. Of these, two patients later decided to undergo a tracheostomy and one patient chose to maintain endotracheal tube intubation. At the end of the study, 37 patients underwent tracheostomy (64.9%), and 20 patients maintained endotracheal tube intubation (35.1%).

In January 2020, we tracked the prognosis of each patient by telephone to ask whether they believed they made an optimal decision marking as a result of the tracheostomy SDM program. The results are listed in Table 4 and table 5. Forty-one patients successfully weaned from the ventilator, including 28 tracheostomy patients and 13 endotracheal tube intubation patients. The successfully weaned patients who underwent tracheostomy was no significantly different from that of those who maintained endotracheal tube intubation (75.7% vs 65.0%, P=0.394).

In terms of survival, twelve patients in the endotracheal tube intubation group expired, but only five in the tracheostomy group. (p=0.001, OR=9.6, 95% confidence interval: 2.618 – 35.207) (table5). In terms of their decision after participating in the tracheostomy SDM program, all participants in the endotracheal tube intubation group believed that they made an optimal decision marking of the tracheostomy SDM program and 32 patients (86.5%) participants in the tracheostomy group believed that they made an optimal decision marking of the tracheostomy SDM program (P=0.999). The reasons for not being satisfied included the following. 1) It is inconvenient to move the tracheostomy tube when the patient's hand flexes. 2) The patient was too old to undergo the operation. 3) No experience of benefit with the tracheostomy. 4) Tracheostomy not considered better than endotracheal tube intubation (two families said). The overall of 91.2% participants believed that they made an optimal decision marking of the tracheostomy SDM program.

Discussion:
In Taiwan, most patients or their families continue to believe many incorrect views about tracheostomy. Many patients or their families will oppose the recommendation to undergo tracheostomy. Thus, the proportion of patients undergoing tracheostomy in Taiwan is much lower than that in the US. The US literature discusses early tracheostomy or late tracheostomy for ICU patients, which provides patients using ventilators a better course of treatment and better prognosis [3-6]. Combes discussed in his study that ICU patients with an early tracheostomy had better survival than those who did not undergo a tracheostomy [7]. In Taiwan, Weng reported that patients with early tracheostomy had fewer ventilator use days, higher weaning rates, and lower in-hospital mortality [8]. In Wu’s study displayed that RCC PMV patients who underwent tracheostomy had a lower in-hospital mortality rate than those who did not [9]. In Huang’s study found a favorable 1-year survival rate for tracheostomy PMV patients, as well as a significantly lower rate of in-hospital mortality [10].

Taiwan’s RCC patients usually must decide whether they need a tracheostomy, not whether to have an early or late tracheostomy. Therefore, we applied the [If my family is difficulty liberated from the ventilator, do he/she need to undergo tracheostomy?] tracheostomy SDM program for these RCC PMV patients. We found no similar article in the international literature and only one case report in Taiwan [11]. Therefore, in the discussion, we can only analyze our research results, and cannot compare these with results from other institutions.

The purpose of step 1 in tracheostomy SDM was to let the patients’ families deeply and correctly understand the difference between tracheostomy and endotracheal tube intubation. We hoped to replace myths with knowledge through step 1. Step 2 shows that patients and their families considered the patient's comfort level as the most important factor in making their decision, placing less importance on the opinions of friends and relatives, but there was no statistically significant difference between groups in attitudes toward patient care. Step 3 tested the knowledge of the patients’ families about tracheostomy and endotracheal tube intubation. This study showed a high degree of knowledge about treatment methods, with a correct answer score of 93.3%. In step 4, only three patients’ families (5.3%) had to discuss with other relatives and friends before making a final
decision. Therefore, the tracheostomy SDM program reached the goal of educating the patients and their families.

Finally, 37 patients chose tracheostomy, and 20 patients chose to maintain endotracheal tube intubation. The results of our follow-up telephone interviews showed that the survival of patients undergoing tracheostomy was excellent (86.5%), but only 86.5% of participants believed that they made an optimal decision marking of the tracheostomy SDM program. Conversely, the survival of patients who maintained endotracheal tube intubation was poor (40%), but all participants believed that they made an optimal decision marking of the tracheostomy SDM program. Although twelve of these maintained endotracheal tube intubation patients died, the family still believed that it was an appropriate treatment choice for the patient. From a prognostic point of view, the survival of patients undergoing tracheostomy is significantly better than that of patients who maintain endotracheal tube intubation. When RCC PMV patients expected to survive for a long time, they are strongly recommended to choose tracheostomy.

Limitations of this study:
The international literature contained no articles of a similar nature for reference. This, it is difficult to place our results in context. Our report is a small study with few participants; it was impossible to make any conclusion from this very preliminary result. We hope to continue to collect patient data, which we will share in the future.

Conclusion
The practice of medical SDM is an ideal model for clinically determining the method of treatment. The clinical application of the tracheostomy SDM program in this study achieved excellent results. The process helped the family and patients better understand what is involved in tracheostomy. The overall of 91.2% participants believed that they made an optimal decision marking of the tracheostomy SDM program. RCC PMV patients who underwent tracheostomy had a longer survival time than those who decided to maintain endotracheal tube intubation.

Declarations
Acknowledgments:
Not applicable.

Authors’ contributions:

Chienhsiu Huang designed the study, collected the data, analyzed the data, wrote the manuscript, and reviewed the manuscript.

Ihung Chen designed and set up [If my family is difficulty liberated from the ventilator, do he/she need to undergo tracheostomy?] tracheostomy shared decision making program.

Ethics approval and consent to participate

The project was approved by Buddhist Dalin Tzu Chi general hospital research ethics committee.

(Approved IRB No.: B10802009)

Consent for publication:

Not applicable.

Competing interests:

The authors declare that they have no competing interests.

Consent

All participants (patients and their family members) provided written informed consent to participate.

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Tables

Table1: Clinical characteristics of study patients (n=57)

| Patients number | Undergo tracheostomy patients | Maintain endotracheal tube intubation patients | Total |
|-----------------|------------------------------|-----------------------------------------------|-------|
| Mean age        | 68.8 Y/O                     | 65.9 Y/O                                      | 69    |
| Sex             |                              |                                               |       |
| male            | 26                           | 13                                           | 39    |
| female          | 11                           | 7                                            | 18    |
| Causes of Respiratory failure |                       |                                               |       |
| pneumonia       | 17                           | 6                                            | 23    |
| Intracranial hemorrhage |              |                                               |       |
| Post operation  | 5                            | 1                                            | 6     |
| Post CPR#       | 4                            | 1                                            | 5     |
| COPD*           | 0                            | 3                                            | 3     |
| miscellaneous   | 7                            | 5                                            | 12    |

#: Cardio-Pulmonary-Cerebral-Resuscitation

*=: Chronic Obstructive Pulmonary Disease
Table 2: The results of step 2: what are the factors you care about? How much the degree you care?

|                                      | Total patients average points | Undergo tracheostomy patients average points | Maintain endotracheal tube intubation patients average points |
|--------------------------------------|------------------------------|---------------------------------------------|-------------------------------------------------------------|
| Willingness of patient               | 3.28                         | 3.24                                        | 3.35                                                        |
| comfort of patient                   | 4.23                         | 4.32                                        | 4.05                                                        |
| Patient can eat or speak             | 3.96                         | 3.92                                        | 4.05                                                        |
| Patient can discharge and return home| 3.89                         | 3.92                                        | 3.85                                                        |
| Mind opinions of friends and relatives| 1.86                         | 1.68                                        | 2.2                                                         |
| Maintain the integrity of the patient's neck | 3.04                         | 2.92                                        | 3.25                                                        |
| affecting patient survival time      | 3.19                         | 2.92                                        | 3.7                                                         |
| complications of a tracheostomy      | 3.68                         | 3.57                                        | 3.9                                                         |
| Complications of endotracheal tube intubation | 3.70                         | 3.62                                        | 3.85                                                        |
| cost of treatment                    | 2.61                         | 2.65                                        | 2.55                                                        |

Table 3: The result of Step 3: How much does the patient or family know about the treatment?
| Correct answer of total patients (%) | Correct answer of undergoing tracheostomy patients (%) | Correct answer of maintaining endotracheal tube intubation patients (%) |
|--------------------------------------|--------------------------------------------------------|---------------------------------------------------------------------|
| After tracheostomy, it will increase the patient’s comfort | 100% | 100% | 100% |
| After tracheostomy, it can reduce oral ulcers and improve oral hygiene. | 100% | 100% | 100% |
| After tracheostomy, it is convenient to clean the sputum in the airway. | 98.2% | 97.3% | 100% |
| After tracheostomy, it may be possible to eat or speak | 94.7% | 94.6% | 95.0% |
| After tracheostomy, it increases the chance of weaning the ventilator | 98.2% | 100% | 95.5% |
| After tracheostomy, the patient must be able to liberate from the ventilator | 78.9% | 81.1% | 75.0% |
| After tracheostomy, the incidence of pneumonia and mortality will reduce. | 87.7% | 89.2% | 85% |
| After tracheostomy, it is safer to replace the artificial airway | 96.5% | 97.3% | 95.0% |
| Tracheostomy will prolong the patient's disease course and increase the burden on the family. | 77.2% | 81.1% | 70.0% |
| Tracheostomy increases the load on the patient and shortens the patient's life. | 98.2% | 97.3% | 100% |
| Once a tracheostomy performs, the tracheostomy tube will never remove. | 93.0% | 94.6% | 90.0% |
| Once a tracheostomy performs, the patient must stay in bed for the rest of his life. | 96.5% | 97.3% | 95.0% |

| correct answer (%) | 93.3% | 94.1% | 91.7% |
Table 4: The outcome of RCC prolonged mechanical ventilation patients discharged status

| RCC discharged status | Total patients | Undergo tracheostomy patients | Maintain e intubation |
|-----------------------|----------------|-------------------------------|-----------------------|
| Transfer to ward      | 41 (71.9%)     | 28 (75.7%)                   | 13 (65.0%)            |
| Transfer to RCW        | 12 (21.1%)     | 8 (21.6%)                    | 4 (20.0%)             |
| Expired in RCC         | 4 (7.0%)       | 1 (2.7%)                     | 3 (15.0%)             |
| total                 | 57 (100%)      | 37 (100%)                    | 20 (100%)             |

Table 5: The result of long-term outcome and satisfaction with their decision of tracheostomy shared decision making program

|                              | Maintain endotracheal tube intubation patients | Undergo tracheostomy patients | p value |
|------------------------------|-----------------------------------------------|-------------------------------|---------|
| Liberater from ventilator    |                                               |                               |         |
| Yes                          | 13 (65.0%)                                    | 28 (75.7%)                   | 0.394   |
| No                           | 7 (35.0%)                                     | 9 (24.3%)                    |         |
| Survival rate                |                                               |                               |         |
| Alive                        | 8 (40%)                                       | 32 (86.5%)                   | 0.001   |
| Death                        | 12 (60%)                                      | 5 (13.5%)                    |         |
| Satisfaction                 |                                               |                               |         |
| Yes                          | 20 (100%)                                     | 32 (86.5%)                   | 0.999   |
| No                           | 0                                             | 5 (13.5%)                    |         |

Supplementary Files
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Appendix.docx