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

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Research article

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Abstract

Background: We applied tracheostomy shared decision-making program for respiratory care center prolonged mechanical ventilation patients. The purpose of this study is to help patients and family members to have an understanding of both the methods of tracheostomy and endotracheal tube. We can then compare the prognostic differences between patients in the program who receive tracheostomy and who continue to maintain endotracheal tube.

Methods: A retrospective cross-sectional study was conducted. The study was performed at the respiratory care center of Dalin Tzu chi hospital from January 2017 to December 2019. We set up a tracheostomy decision-making program. The medical team identified eligible patients. We conduct semi-structured interviews to individual family members. We tracked the survival of each patient and confirmed the satisfaction of the patient or family members with taking part of the tracheostomy shared decision-making program in January 2020. Data of patients who participated in tracheostomy shared decision-making program were collected and analyzed.

Results: Fifty-seven respiratory care center patients attended the tracheostomy shared decision-making program. 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 regarding the methods of treatment in the two groups of patients. Patients or family members of the two groups have a good understanding of the two methods of treatment. The survival rate of patients undergoing tracheostomy was 86.5% and 86.5% of participants believed that they made an optimal decision based on the result of the tracheostomy shared decision-making program. The survival rate of patients who maintained endotracheal tube intubation was 40%, and the all of participants believed that they made an optimal decision based on the result of the tracheostomy shared decision-making program. Patients who underwent tracheostomy have a favorable survival rate.

Conclusions: The clinical application of tracheostomy shared decision-making program ensures that patients and family members have a clearer understanding of the methods of tracheostomy and endotracheal tube treatment. Overall, 91.2% of the participants believed that they made an optimal decision despite of the end result.

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, based on the experiences in promoting of patient safety and evidence-based medicine, a nationwide shared decision making project has been launched since 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 of concern and the degree of concern regarding the methods of treatment. Then, patient decides the best option among all feasible treatments. Expect to achieve the goal of two-way communication. The decision making of the program “If my family has difficulty liberating from the ventilator, do he/she need to undergo tracheostomy?” was developed under the Ministry of Health and Welfare's "Medical and Disease Sharing Decision Promotion Plan".


“The Trial Plan for National Public Health Insurance Ventilator Dependent Patients Comprehensive Care System” has been promoted in Taiwan since 2000. 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 family members 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 members. 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 family members 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. Thus, the proportion of patients undergoing tracheostomy in Taiwan is lower than that in the US. In Taiwan Clinical Performance Indicators data revealed the tracheostomy rate of RCC prolonged mechanical ventilation patients in medical center was about 39%. 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. Combes discussed in his study that ICU patients with an early tracheostomy had better survival than those who did not undergo a tracheostomy. In Taiwan, Weng reported that patients with early tracheostomy had fewer ventilator use days, higher weaning rates, and lower in-hospital mortality. In Wu’s study display that RCC PMV patients who underwent tracheostomy had a lower in-hospital mortality rate than those who did not. 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. Taiwan's RCC PMV patients usually must decide whether they need a tracheostomy, not
whether to have an early or late tracheostomy. Dalin Tzu Chi Hospital have applied shared decision making in 2017 to implement the program “If my family has difficulty liberating from the ventilator, do he/she need to undergo tracheostomy?”. In this study, we try to understand how patients or family members benefit for the program and develop better understanding of both the methods of tracheostomy and endotracheal tube. We also compare the prognostic differences between patients receiving tracheostomy and patients who continue to maintain endotracheal tube, which serves as the basis for us to provide suggestions for the patients or family members in the shared decision-making program. Our research objectives are to correct the misconception of patients or family members about tracheostomy and to increase the number of PMV patients undergoing tracheostomy. This study also provides preliminary results of tracheostomy sharing decision-making program in RCC PMV patients with the medical community.

**Methods**

Study design:

A retrospective cross-sectional study was conducted. The study was performed at the respiratory care center of Dalin Tzu Chi hospital from January 2017 to December 2019. Detailed related to the methods of the study, the decision-making program and the measurement of decision-making outcomes were provided below. 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 or family members) provided written informed consent to participate.

Program steps:

We set up a tracheostomy decision-making program (appendix). The goals of this program are to: 1. Educate patients and family members to understand the differences, advantages and disadvantages of the two treatment methods (tracheostomy and endotracheal tube intubation); 2. Understand the factors of concern and the degree of concern related to the two methods of treatment within patients and family members. 3. Help patients and family members to decide on the method of treatment. The tracheostomy SDM program included four steps. In step one, patients and family members were invited to compare the advantages, risks, side effects, complications, costs, and alternatives of each option. In step two, during the process of they chose a treatment, participants were asked about the factors of concern and the degree of concern to the two methods of treatment. In step three, we tested the knowledgeability of the patient or family related to the two methods of treatment. In step four, we asked the patient or family members to evaluate their decision about the treatment method.

Theoretical framework: (Figure 1)

Participant selection:
Dalin Tzu Chi hospital is a tertiary general hospital. Our RCC is a weaned unit in acute-care hospitals for prolonged mechanical ventilation patients. There are 10 bed in our RCC. In the past three years, an average of 127 PMV patients were hospitalized each year. All patients with prolonged mechanical ventilation who were admitted to Dalin Tzu Chi hospital respiratory care center during the study period were invited for participation. Excluded criteria: 1. The patient's clinical condition is expected to die in the near future; 2. The patient's clinical condition is expected to be detached from the ventilator in the near future; 3. The patient or family members do not accept tracheostomy at all and are unwilling to understand the tracheostomy shared decision-making program; 4. The surgeon determines that the patient has no indication for tracheostomy or a high risk of patient undergoing tracheostomy; 5. Patient has received tracheostomy before admitted to RCC.

Interventions:

Eligible study medical team included RCC physician and RCC nurses. Due to the fact that most RCC PMV patients could not talk and were in unclear consciousness status, the participants were the family members. The medical team identified eligible patients after family members agreed to take part. We chose to conduct semi-structured interviews with individual family members. Additional written informed consents were taken from individual participants prior to each interview. After patients transferred out of the RCC, we tracked the survival of each patient and the satisfaction of the patient or family members with the tracheostomy SDM program. Interviews were conducted over the phone by RCC head nurse in January 2020.

Outcomes measure:

We explore whether the following aspects of the two groups (patients undergoing tracheostomy versus patients maintaining endotracheal tube intubation) are statistically different.

1. The factors of concern regarding two treatment methods
2. The degree of concern regarding two treatment methods
3. The correct answer rate of two treatment methods test
4. Ventilator weaned rate
5. Survival rate
6. Satisfaction rate of tracheostomy shared decision-making 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 and step 2 were evaluated using the Student’s t-test for continuous variables and Pearson chi-square tests or Fisher’s exact test for categorical variables. Step 3, the survival of patients, the successfully weaned patients, and satisfaction of the patients or family members with the use of the
tracheostomy SDM program were evaluated using logistic regression analysis. 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 which accounted for 15.0% of patients during this period. The clinical data of the patients is 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 is 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 difference in response between the two groups of patients was not statistically significant.

The results of the test of family members 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 difference 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 making 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 rate of patients who underwent tracheostomy was no significantly different from that of those who maintained endotracheal tube intubation (75.7% vs 65.0%, P=0.538).

In terms of survival, twelve patients in the endotracheal tube intubation group died, 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 making of the tracheostomy SDM program and 32 patients (86.5%) participants in the tracheostomy group believed that they made an optimal decision making of the tracheostomy SDM program. 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 (family members from two different patient cases). The overall of 91.2% participants believed that they made an optimal decision making of the tracheostomy SDM program.

Discussion

We applied the program “If my family has difficulty liberating 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 family members 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. The Influencing factors related to tracheostomy are maintaining the integrity of the patient's neck, surgery affecting patient survival time, and the complications of the tracheostomy. The group of patients maintaining endotracheal tube has a higher degree of such concern, thus reduces the family members’ willingness that patient undergo tracheostomy. 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%. The correct rate of three questions was below 90% (1. Tracheostomy will prolong the patient's disease course and increase the burden on the family; 2. After tracheostomy, the patient must be able to liberate from the ventilator; 3. After tracheostomy, the incidence of pneumonia and mortality will reduce). When comparing the two treatment methods, we need to explain in more detail of these three questions so that the family members can have a more accurate understanding. 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 family members.

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%). Conversely, the survival of patients who maintained endotracheal tube intubation was poor (40%), but all participants believed that they made an optimal decision making of the tracheostomy SDM program. Although twelve of these maintained endotracheal tube intubation patients died, the family members 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:

Our report is a small retrospective study with few participants. There is no control group to compare the difference after exposure to the tracheostomy SDM program intervention. It is impossible to make any firm conclusion from this preliminary result. We hope to conduct a control study which will be shared in the future.

Conclusion

The clinical application of tracheostomy shared decision-making program achieved that patients and family members have a clearer understanding of the methods of tracheostomy and endotracheal tube treatment. The overall of 91.2% participants believed that they made an optimal decision.

Declarations

Ethics approval and consent to participate: The project was approved by 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.

Consent for publication: Not applicable.

Availability of data and materials: Data availability in Supplementary Material

Competing interests: The authors declare that they have no competing interests.

Funding: There was no funding in this study.

Authors' Contributions: C Huang designed the study, collected the data, analyzed the data, wrote the manuscript, and reviewed the manuscript.

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

Acknowledgments: Not applicable.

References

1. United States: The ethical and legal implications of informed consent in the patient-practitioner relationship. United States. President's commission for the study of ethical problems in medicine and


Tables

Table1: Clinical characteristics of study patients (n=57)
Patients number | Undergo tracheostomy patients | Maintain endotracheal tube intubation patients | P value (Odd Ratios)
---|---|---|---
Sex | | | |
male | 26 | 70.3 | 13 | 65 | 0.769 | 0.786
female | 11 | 29.7 | 7 | 35 | 0.769 | 1.273
Causes of Respiratory failure | | | |
pneumonia | 17 | 46.0 | 6 | 30 | 0.273 | 0.504
Intracranial hemorrhage | 4 | 10.8 | 4 | 20 | 0.432 | 2.063
Post operation | 5 | 13.5 | 1 | 5 | 0.410 | 0.337
Post CPR# | 4 | 10.8 | 1 | 5 | 0.647 | 0.434
COPD* | 0 | 0 | 3 | 15 | 0.039 | 1.176
miscellaneous | 7 | 18.9 | 5 | 25 | 0.736 | 1.429

#: Cardio-Pulmonary-Cerebral-Resuscitation
*: Chronic Obstructive Pulmonary Disease

Table 2: The results of step 2: what are the factors you concern? to what degree do you concern?

<table>
<thead>
<tr>
<th>Willingness of patient</th>
<th>Undergo tracheostomy patients</th>
<th>Maintain endotracheal tube intubation patients</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>average points</td>
<td>average points</td>
<td></td>
<td></td>
</tr>
<tr>
<td>average points</td>
<td>average points</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Willingness of patient</td>
<td>3.24</td>
<td>3.35</td>
<td>0.778</td>
</tr>
<tr>
<td>Comfort of patient</td>
<td>4.32</td>
<td>4.05</td>
<td>0.280</td>
</tr>
<tr>
<td>Patient can eat or speak</td>
<td>3.92</td>
<td>4.05</td>
<td>0.693</td>
</tr>
<tr>
<td>Patient can discharge and return home</td>
<td>3.92</td>
<td>3.85</td>
<td>0.821</td>
</tr>
<tr>
<td>Opinions of friends and relatives</td>
<td>1.68</td>
<td>2.2</td>
<td>0.209</td>
</tr>
<tr>
<td>Maintain the integrity of the patient's neck</td>
<td>2.92</td>
<td>3.25</td>
<td>0.462</td>
</tr>
<tr>
<td>Surgery affecting patient survival time</td>
<td>2.92</td>
<td>3.7</td>
<td>0.078</td>
</tr>
<tr>
<td>Complications of a tracheostomy</td>
<td>3.57</td>
<td>3.9</td>
<td>0.376</td>
</tr>
<tr>
<td>Complications of endotracheal tube intubation</td>
<td>3.62</td>
<td>3.85</td>
<td>0.539</td>
</tr>
<tr>
<td>Cost of treatment</td>
<td>2.65</td>
<td>2.55</td>
<td>0.805</td>
</tr>
</tbody>
</table>
Table 3: The result of Step 3: How much does the patient or family know about the treatments?

<table>
<thead>
<tr>
<th>Event</th>
<th>Correct answer of undergoing tracheostomy patients (%)</th>
<th>Correct answer of maintaining endotracheal tube intubation patients (%)</th>
<th>p-value (Odd Ratio)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After tracheostomy, it will increase the patient's comfort</td>
<td>100%</td>
<td>100%</td>
<td>NA</td>
</tr>
<tr>
<td>After tracheostomy, it can reduce oral ulcers and improve oral hygiene.</td>
<td>100%</td>
<td>100%</td>
<td>NA</td>
</tr>
<tr>
<td>After tracheostomy, it is more convenient to clean the sputum in the airway.</td>
<td>97.3%</td>
<td>100%</td>
<td>1.000(1.028)</td>
</tr>
<tr>
<td>After tracheostomy, it may be possible to eat or speak</td>
<td>94.6%</td>
<td>95.0%</td>
<td>1.000(1.086)</td>
</tr>
<tr>
<td>After tracheostomy, it increases the chance of weaning the ventilator</td>
<td>100%</td>
<td>95.5%</td>
<td>0.351(0.950)</td>
</tr>
<tr>
<td>After tracheostomy, the patient must be able to liberate from the ventilator</td>
<td>81.1%</td>
<td>75.0%</td>
<td>0.736(0.700)</td>
</tr>
<tr>
<td>After tracheostomy, the incidence of pneumonia and mortality will reduce.</td>
<td>89.2%</td>
<td>85%</td>
<td>0.687(0.687)</td>
</tr>
<tr>
<td>After tracheostomy, it is safer to replace the artificial airway</td>
<td>97.3%</td>
<td>95.0%</td>
<td>1.000(0.528)</td>
</tr>
<tr>
<td>Tracheostomy will prolong the patient's disease course and increase the burden on the family.</td>
<td>81.1%</td>
<td>70.0%</td>
<td>0.509(0.544)</td>
</tr>
<tr>
<td>Tracheostomy increases the load on the patient and shortens the patient's life.</td>
<td>97.3%</td>
<td>100%</td>
<td>1.000(1.028)</td>
</tr>
<tr>
<td>Once a tracheostomy performs, the tracheostomy tube can never remove.</td>
<td>94.6%</td>
<td>90.0%</td>
<td>0.607(0.514)</td>
</tr>
<tr>
<td>Once a tracheostomy performs, the patient must stay in bed for the rest of his life.</td>
<td>97.3%</td>
<td>95.0%</td>
<td>1.000(0.528)</td>
</tr>
<tr>
<td><strong>correct answer (%)</strong></td>
<td><strong>94.1%</strong></td>
<td><strong>91.7%</strong></td>
<td><strong>0.262(0.684)</strong></td>
</tr>
</tbody>
</table>

Table 4: The discharged status of RCC prolonged mechanical ventilation patients
<table>
<thead>
<tr>
<th>Discharged status</th>
<th>Undergo tracheostomy patients ($n=37$)</th>
<th>Maintain endotracheal tube intubation patients ($n=20$)</th>
<th>P value (Odd Ratios)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfer to ward</td>
<td>28 (75.7%)</td>
<td>13 (65.0%)</td>
<td>0.538 (1.675)</td>
</tr>
<tr>
<td>Transfer to RCW</td>
<td>8 (21.6%)</td>
<td>4 (20.0%)</td>
<td>1.000 (1.013)</td>
</tr>
<tr>
<td>Died in RCC</td>
<td>1 (2.70%)</td>
<td>3 (15.0%)</td>
<td>0.119 (0.157)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Liberated from ventilator</th>
<th>Undergo tracheostomy patients ($n=37$)</th>
<th>Maintain endotracheal tube intubation patients ($n=20$)</th>
<th>P value</th>
<th>Odd Ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>28 (75.7%)</td>
<td>13 (65.0%)</td>
<td>0.538</td>
<td>1.675</td>
</tr>
<tr>
<td>No</td>
<td>9 (24.3%)</td>
<td>7 (35.0%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Survival rate</th>
<th>Undergo tracheostomy patients ($n=37$)</th>
<th>Maintain endotracheal tube intubation patients ($n=20$)</th>
<th>P value</th>
<th>Odd Ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alive</td>
<td>32 (86.5%)</td>
<td>8 (40%)</td>
<td>0.001</td>
<td>9.6</td>
</tr>
<tr>
<td>Death</td>
<td>5 (13.5%)</td>
<td>12 (60%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Satisfaction</th>
<th>Undergo tracheostomy patients ($n=37$)</th>
<th>Maintain endotracheal tube intubation patients ($n=20$)</th>
<th>P value</th>
<th>Odd Ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>32 (86.5%)</td>
<td>20 (100%)</td>
<td>0.151</td>
<td>0.865</td>
</tr>
<tr>
<td>No</td>
<td>5 (13.5%)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figures
Figure 1

Theoretical framework

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.
• Appendix.docx
• NEWSDMTRACSPSS.xlsx