臺北醫學大學・市立萬芳醫院
Taipei Medical University - Wan Fang Hospital

CRITICAL CARE

引言人：柳玉芳

Journal Club

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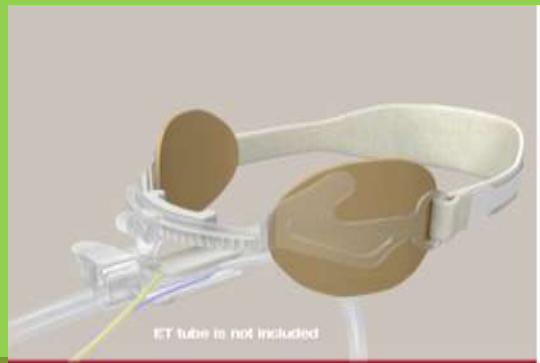

背景資料 *Background Knowledge*

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The development of medical device-related pressure ulcers (MDR PUs) as a result of an endotracheal tube fixator (ETTF) use affects patients particularly in the intensive care unit (ICU).

three types of endotracheal tube fixations

https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.youtube.com%2Fwatch%3Fv%3DQ2dDphIOtVk&psig=AOvVaw262aGzQBH89ByPMgmv3xNc&ust=1620547588317000&source=images&cd=vfe&ved=2ahUKEwjfhYKs0LnwAhUTNqYKHX63A_wQr4kDegUIARCgAQ

各種氣管內管固定器

臺安醫院
慈濟學校財團法人慈濟科技大學*

https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.tahsda.org.tw%2Fdepartments%2Ffiles%2F%25E8%25AD%25B7%25E7%2590%2586%25E9%2583%25A8-ALL%2520IN%2520ONE%2520%25E8%25A4%2587%25E5%2590%2588%25E8%25A9%25A6%25E7%25AE%25A1%25E8%25B7%25AF%25E5%259B%25BA%25E5%25AE%259A%25E5%2599%25A8.pdf&psig=AOvVaw1Np1jasVDAY3Vo87yHxSei&ust=1620647779804000&source=images&cd=vfe&ved=0CAIQjRxqFwoTCODug87FvPACFQAAAAAdAAAAABAD

銘成儀器
http://www.minchern.com.tw/product6.33.htm

https://www.google.com/url?sa=i&url=https%3A%2F%2Flaerdal.com%2Fcn%2Fproducts%2Fmedical-devices%2Fairway-management%2Fthomas-tube-holder%2F&psig=AOvVaw1Q5zN_vNEYs1jaQgdxubMG&ust=1620648480220000&source=images&cd=vfe&ved=0CAIQjRxqFwoTCKiCvp_IvPACFQAAAAAdAAAAABAJ

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Research article

Under (less) pressure – Facial pressure ulcer development in ventilated ICU patients: A prospective comparative study comparing two types of endotracheal tube fixations

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InCites Journal Citation Reports — Clarivate

Intensive and Critical Care Nursing

TITLES
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JCR Abbrev: INTENS CRIT CARE NUR

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Current Year | 2018 | 2017 | All Years

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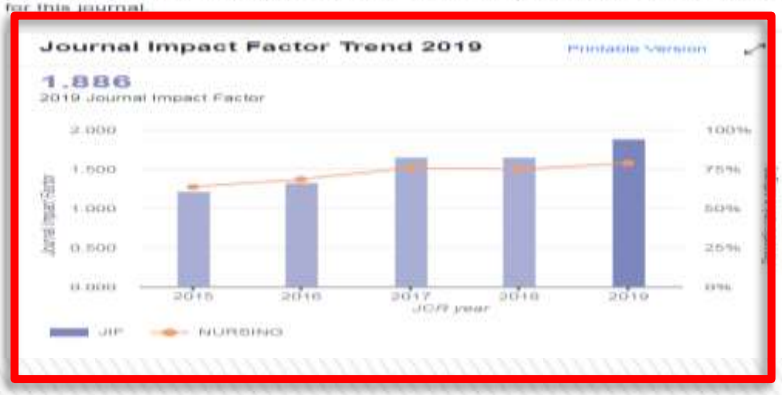

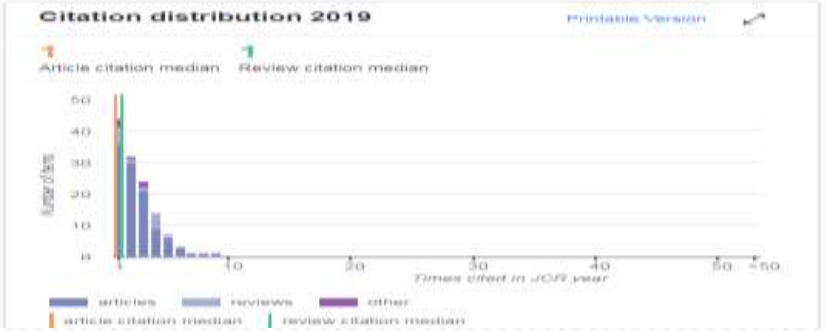

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Taipei Medical University - Wan Fang Hospital

RCT Appraisal sheets(RAMbo)

Appraisal Tool [RCT]

步驟1: 研究探討的問題為何? (PICO)

步驟2：研究的品質有多好? (內在效度)

步驟3: 研究結果的意義為何? (效益)

研究探討的問題為何?

P

- 放置氣管內管的病人

I

- 使用氣管內管固定器

C

- 非使用氣管內管固定器(膠帶固定、棉繩固定)

O

- 臉部皮膚損傷情形

RCT Appraisal sheets(RAMbo)

Appraisal Tool [RCT]

步驟1:研究探討的問題為何?

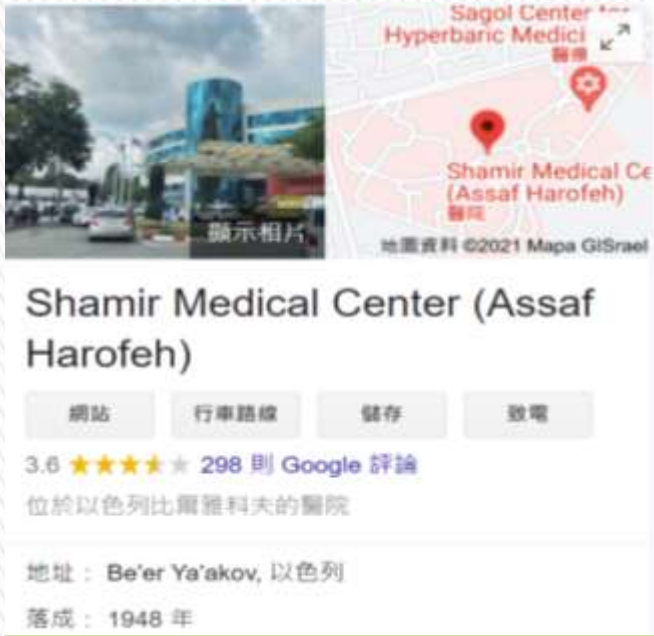
步驟2: 研究的品質有多好? (內在效度)

步驟3: 研究結果的意義為何? (效果)

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

是

2-1.招募(Recruitment)-受試者是否具有代表性?



Objectives

The aim of this prospective comparative study was to determine the incidence of MDR PUs among patients using the different ETTFs (CT-ETTF and AF-ETTF)

Study location and ethical consideration

The study was conducted in an 18-bed general ICU in large general hospital in central part of Israel. No changes in admission policy or bed occupancy occurred during the 3.5-year research period(2014–2017).

Approval for the research was obtained from the local Institutional Review Board (IRB) (approval 106/16 and 216/13).

Research design

Both groups were based on a convenience sample and had the same inclusion criteria that included: first mechanical ventilation event during current hospitalisation, no existing facial wounds or pressure ulcers at time of admission to the ICU and intubation performed in the ICU or within two hours prior to ICU arrival.

否

2-2. 分派(Allocation)-分派方式是否隨機且具隱匿性.....?p.2

Research design

Our study was a prospective comparative study that followed two similar groups of ICU ventilated patients for the development of MDR PUs. Group A was treated with cloth tape ETTF (CT-ETTF), while Group B was treated with the Anchorfast Hollister ETTF (AHETTF). Both groups were based on a convenience sample and had the same inclusion criteria that included: first mechanical ventilation event during current hospitalisation, no existing facial wounds or pressure ulcers at time of admission to the ICU and intubation performed in the ICU or within two hours prior to ICU arrival.

分派方式未說明是否隨機
且具隱匿性

步驟 2: Validity（族群代表性合適、結果可靠、精確）？

2-3. ...每個組別在研究開始時的情況是否相同?p.2

是

Table 2
Demographic data.

	Group A (N = 78)	Group B (N = 77)	Statistical test value, p value
Age M(±)	70.76 (±15.26)	71.04 (±15.73)*	t = −0.113; 0.91
Gender (male) – n (%)	42 (53.8%)	44 (57%)	χ^2 = 0.171, p = 0.68
Albumin upon admission M(±)	29.18 (±6.84) g/L	29.87 (±7.12) g/L	t = −0.62; 0.54
DM diagnosis	31 (39.7%)	30 (39.0%)	χ^2 = 0.01, p = 0.92

* Unknown age in one case.

P>0.05，兩組條件相當

Table 1
Main diagnosis on admission to ICU.

Diagnosis upon admission	Total N (%)	Group A, n (%)	Group B, n (%)
Pulmonary or respiratory emergency	84 (54%)	39 (50%)	45 (58%)
Septic shock/sepsis	29 (19%)	14 (18%)	15 (19%)
Emergency neurological or neurosurgical conditions (stroke/neurosurgery)	20 (13%)	9 (12%)	11 (14%)
Trauma	7 (5%)	6 (8%)	1 (1%)
Post-surgical recovery	8 (5%)	5 (6%)	3 (4%)
Emergency cardiac conditions (MI)	1 (1%)	1 (1%)	0
Haematological conditions	4 (3%)	4 (5%)	0
Post-CPR	2 (1%)	0	2 (3%)
Total	155	78 (100%)	77 (100%)

步驟 2: Validitv（族群代表性合適、結果可靠、精確）？

2-4.維持(Maintenance)-各組是否給予相同的治療?p.3

是

Data collection

Group A was treated with CT-ETTF, as per facility policy. This included a mandatory daily cloth tape replacement performed by two critical care registered nurses (CCRNs) or less commonly, by a CCRN and an ICU physician.

Group B was treated with AF-ETTF as per facility policy and manufacturer recommendations. Application of the AF-ETTF was also performed by two CCRNs or, less commonly, by a CCRN and an ICU physician

皆由2為重症護理師一同協助

2-5.....是否有足夠的追蹤(Follow up)?說明:

是

Sample size in both groups was based on 0.8 power, alpha = 0.05, and a medium population effect size demanding 64 patients in each group (Cohen, 1992). Due to lost for follow up patients, we increased the population in both groups by 25% to 80.

Group A (N = 78) prior to the introduction of AF-ETTF into the department (2014–2015).

Data collection from Group B (N = 77) began six months after the introduction of the AH-ETTF to the department in 2015 and after data collection for Group A was completed. Data collection from Group B was performed during 2016–2017.

文章沒有說明個案流失的原因

2-6.評估(Measurement)-受試者與評估者是否對治療方式及(或)評估目的維持盲法(Blind)? 說明：p3(Blind)

是

Data collection

Group A was treated with CT-ETTF, as per facility policy. This included a mandatory daily cloth tape replacement performed by two critical care registered nurses (CCRNs) or less commonly, by a CCRN and an ICU physician. In our unit, gauze pads on pressure sites (ears, lips, cheeks) were used as a method of routine protection from MDR PU development. The time required for the CCRNs to compete the procedure was estimated based on researcher observation; the observed CCRNs were unaware that they were being observed.

受試者不知被觀察

Group B was treated with AF-ETTF as per facility policy and manufacturer recommendations. Application of the AF-ETTF was also performed by two CCRNs or, less commonly, by a CCRN and an ICU physician. Unlike CT-ETTF, AF-ETTF does not require daily changing. The time required for the CCRNs to compete the procedure was estimated based on researcher observation; once again the CCRNs were unaware that they were being observed

Appraisal Tool [RCT]

步驟1:研究探討的問題為何?

步驟2: 研究的品質有多好? (內在效度)

步驟3: 研究結果的意義為何? (效果)

步驟3：研究結果的意義為何?

使用何種評估方式，療效有多大？NNT(=1/ARR)
這個研究結果是否可能隨機(巧合)發生? 說明：p value&CI

Table 3
Clinical data.

	Group A (N = 78)	Group B (N = 77)	Statistical test value, p value
Hospital days until PU formation	6.07	15.29	$t = -3.45$; $p < 0.01$**
Ventilation Days Until PU formation	5.04	13.86	$t = -3.74$; $p < 0.01$**
PU formation	45	7	$t = 7.45$; $p < 0.01$**

** Indicates statistical significance.

步驟 3: 研究結果的意義為何?

Table 4
ETT-MDR PU Location.

	Group A (n = 78), n (%)	Group B (n = 77), n (%)	Total (N = 155)
No PU	*33 (42%)*	*70 (91%)*	*103*
Right Ear	9 (11.5%)	0	9
Both Ears	9 (11.5%)	0	9
Right Ear and Lip	2 (2.5%)	0	2
Left Ear	18 (23%)	1 (1.3%)	19
Left Ear and Lip	1 (1%)	0	1
Lip	6 (8%)	4 (5%)	10
Right cheek	0	1 (1.3%)	1
Right & Left cheek	0	1 (1.3%)	1
Total ETTF MDR PU	45 (58%)	7 (9%)	52 (33.5%)

Table 5
ETT-MDR PU grade at time of discovery.

PU grade	Group A (n = 78), n (%)	Group B (n = 77), n (%)	Total (n = 155)
1	20 (25.6%)	0	20
2	23 (29.5%)	7 (9%)	30
3	2 (2.6%)	0	2
Total	45 (58%)	7 (9%)	52

步驟 3: 研究結果的意義為何? p3

1. Average application time for CT-ETTF and AF-ETTF was almost identical: average 4:04 minutes and 4:05 minutes respectfully, (eight minutes of nurse time per procedure, since two nurses are necessary for the procedure as per facility policy).
2. However, the CT-ETTF required that same amount of time (eight minutes) daily for the cloth tape change while AF-ETTF did not.
3. Moreover, we disregarded the time spent for allocating the accompanying CCRN for the procedure, focusing on application time only.

步驟 3: 研究結果的意義為何? p3

4. Group A :Our study found that MDR PU is almost twice as likely to develop on the left side (in particular the left ear) compared to the right side. We believe that this difference is due to the location of the ventilator and ventilation tubes, which is on the left side of the patient in this ICU, resulting in less accessibility to the left side for assessment and prevention.
5.Our research makes an additional distinction among ETTF type in relation to MDR PU.
We found a lower MDR PU development rate on patients' lips in favour of AF-ETTF.
This is consistent with recent RCT research findings (Landsperger et al., 2019).

RCT Appraisal sheets(RAMbo)

RESEARCH Open Access

A randomized clinical trial for the timing of tracheotomy in critically ill patients: factors precluding inclusion in a single center study

Appraisal [RCT]-結論
（內在效度 & 結果 ）

-內在效度

1.招募(Recruitment)-受試者是否具有代表性？ YES

2. 分派(Allocation)-分派方式是否隨機且隱匿性？ NO

3. ....每個組別，在研究開始時的情況是否相同？ YES

4. 維持(Maintenance)-各組是否給予相同的治療? YES

5.....是否有足夠的追蹤(Follow up)? YES

6. 評估(Measurement)-受試者與評估者是否對治療方式及(或)評估目的維持盲法(Blind)? YES

「效度」(validity)

7. 使用何種評估方式，療效有多大? NNT(=1/ARR) YES

8. 這個研究結果是否可能隨機(巧合)發生? No

「效益」(importance)

Research article

Under (less) pressure – Facial pressure ulcer development in ventilated ICU patients: A prospective comparative study comparing two types of endotracheal tube fixations

Michael Kuniavsky [a,b,c,*], Evgeny Vilenchik [a], Alina Lubanetz [a]

[a] Assaf Harofeh (Shamir) Medical Center, General ICU, Israel
[b] Health Research Department, Ministry of Health, Jerusalem, Israel
[c] The Hebrew University School of Public Health and Community Medicine, Faculty of Medicine, Jerusalem, Israel

結論

- The differences we found in MDR PU rate between the different ETTF types are significant and should be taken into consideration when deciding the type of ETTF to employ.
- Our study is limited by the relatively small population sample and lack of randomisation.
- Moreover, we compare standard cloth tape fixation to AH-ETTF while there are a variety of other ETTF types available on the market that can be evaluated.
- Further research is needed to find the optimal options for ventilated patients ETTF in regards to lowering the risk of MDR PU development.
- Based on the findings of the study, an economical research should be conducted to compare the cost differences between standard ETTF and AF-ETTF as well as staff time required for each type of ETTF implementation.

Implications for clinical practice

- Pressure ulcers related to endotracheal tube fixators are common and important issue.
- Incidence of Pressure ulcers related to Enotracheal Tube Fixators may be as high as 58% when using standard cloth tape Endotracheal Tube Fixators.
- Incidence of the pressure ulcers may vary related to Endotracheal Tube Fixators type.
- Using appropriate Endotracheal Tube Fixators may reduce development of pressure ulcers.

Landsperger et al. Critical Care (2019) 23:161
https://doi.org/10.1186/s13054-019-2440-7

Critical Care

RESEARCH Open Access

The effect of adhesive tape versus endotracheal tube fastener in critically ill adults: the endotracheal tube securement (ETTS) randomized controlled trial

Janna S. Landsperger[1,3*], Jesse M. Byram[1], Bradley D. Lloyd[2], Todd W. Rice[1] and for the Pragmatic Critical Care

Methods: In this pragmatic, single-center, randomized trial, critically ill adults admitted to the medical intensive care unit (MICU) and expected to require invasive mechanical ventilation for greater than 24 h were randomized to adhesive tape or endotracheal tube fastener at the time of intubation. The primary endpoint was a composite of any of the following: presence of lip ulcer, endotracheal tube dislodgement (defined as moving at least 2 cm), ventilator-associated pneumonia, or facial skin tears anytime between randomization and the earlier of death or 48 h after extubation. Secondary endpoints included duration of mechanical ventilation and ICU and in-hospital mortality.

Results: Of 500 patients randomized over a 12-month period, 162 had a duration of mechanical ventilation less than 24 h and 40 ha 5
evaluable patients r
primary endpoint o
patients in the adhe
days, respectively (p
versus 19.5 per 1000
tube was dislodged
tape group ($p = 0.03$
similar between the

Conclusion: The us a
composite outcom
adhesive tape.

(Continued on next page)

2019年隨機分配的500名

153名患者被隨機分配到氣管內管固定帶
145名患者被隨機分配到膠帶。兩組之間的基本特性相同。

結論
與膠帶相比，使用氣管內管固定器降低了複合結果的發生率，包括唇潰瘍，面部皮膚撕裂或氣管插管移位。

主要結果

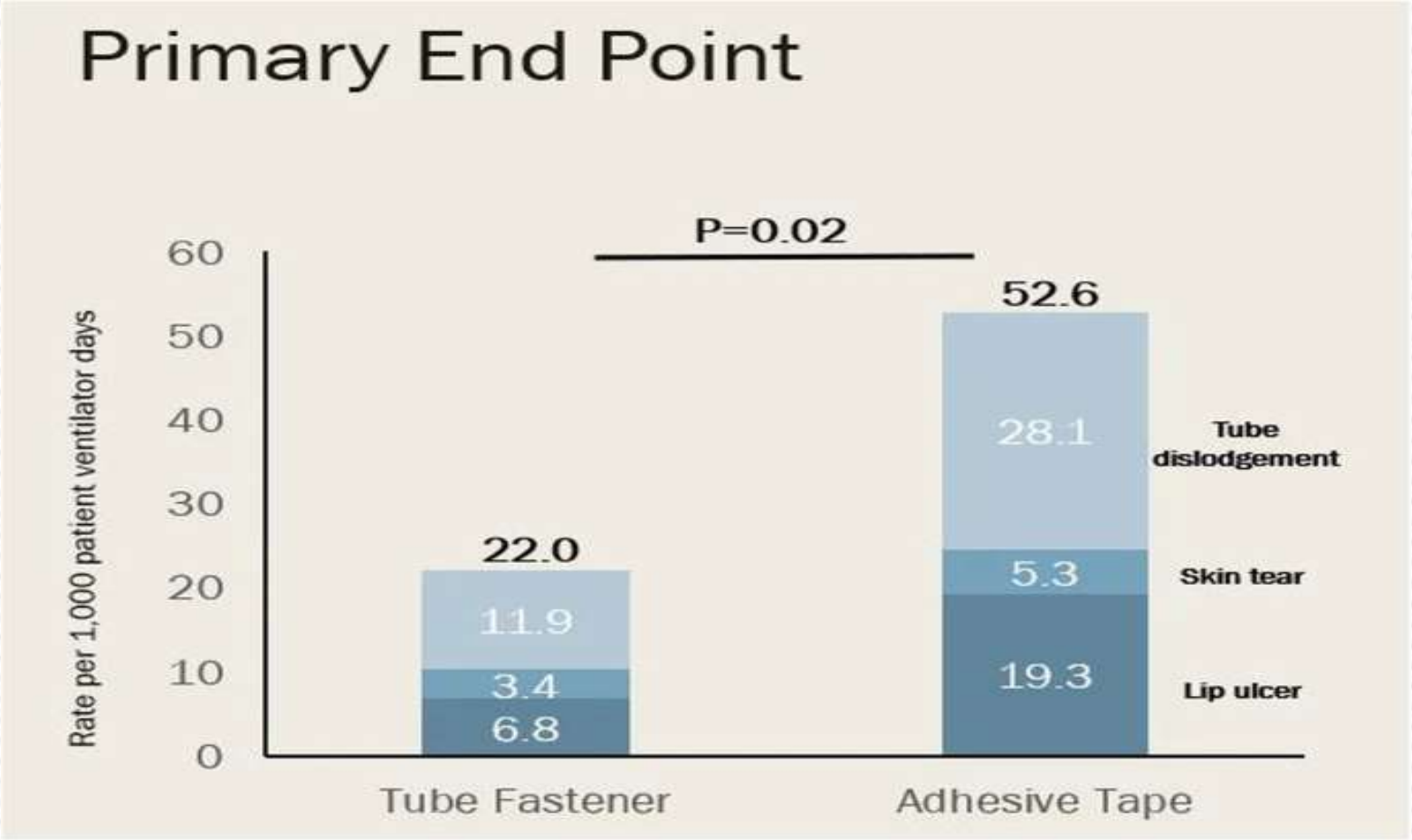


Table 2 Clinical outcomes

Outcome	Tube fastener ($n = 153$)	Adhesive tape ($n = 145$)	p value
Primary outcome			
Lip ulcers, skin tear, tube dislodgement, or ventilator-associated pneumonia—no. of patients (%)	12 (7.8)	25 (17.2)	0.014
Rate of primary outcome (per 1000 patient ventilator days) (95% CI)	22.0 (16.3–27.7)	52.6 (47.4–57.8)	0.020
Components of primary outcome			
Lip ulcer—no. (%)	4 (2.6)	11 (7.3)	0.050
Rate per 1000 patient ventilator days	6.8 (5.6–8.0)	19.3 (17.1–21.6)	0.052
Skin tear—no. (%)	2 (1.4)	3 (2.1)	0.610
Rate per 1000 patient ventilator days	3.4 (2.0–4.8)	5.3 (4.7–5.9)	0.622
Tube dislodgement*—no. (%)	6 (3.9)	15 (10.3)	0.030
Rate per 1000 patient ventilator days	11.9 (6.5–17.3)	28.1 (24.4–31.8)	0.035
Secondary outcomes			
ETT repositioned—no. (%)	17 (12.1)	40 (29.0)	< 0.001
Self-extubations—no. (%)	2 (1.3)	2 (1.4)	0.957
Ventilator-associated pneumonia	0 (0)	0 (0)	N/A
MV duration (days)	3.9 ± 3.0	3.9 ± 3.4	0.75
ICU mortality—no. (%)	52 (34.0)	51 (35.2)	0.83
Hospital mortality—no. (%)	57 (37.3)	54 (37.2)	0.99

Data are reported as no. (%), rate per 1000 patient ventilator days (95% CI), or mean ± standard deviation
*Tube dislodgement defined as or needing to reposition the endotracheal tube more than 1 cm

» 臨床專家

討論

» 是否贊成以氣管內管固定器取代布膠固定，以降低醫源性壓傷?

同意：5票

仍有疑慮：24票

不同意：3票