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Supplementary appendix

This appendix formed part of the original submission. We post it as supplied by the authors.

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Appendix

1 Methods

1.1 Assessment of the risk of bias for cluster randomized controlled trials (RCTs)

We assessed the risk of bias in cluster RCTs using the Cochrane collaboration risk of bias tool for cluster RCTs[1]. The tool consists of five domains (domain 1a: Risk of bias arising from the randomization process; domain 1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial; domain 2: Risk of bias due to deviations from the intended interventions; domain 3: Risk of bias due to missing outcome data; domain 4: Risk of bias in measurement of the outcome; and domain 5: Risk of bias in selection of the reported result). The overall risk of bias is graded as high, low, or having some concerns based on the following criteria:

- High risk of bias: 1) the result of interest is judged to be at high risk of bias regarding at least one of the five domains; or 2) the study is judged to have some concerns that substantially lower the confidence in the result in multiple domains.

- Some concerns: the result of interest is judged to have some concerns in at least one domain, but not to be at high risk of bias regarding any domain.

- Low risk of bias: the result of interest is judged to be at low risk of bias regarding all domains.

1.2 Data analysis

Clustering effect was calculated based on the following formula, with the events and totals rounded to the nearest integer:

- *M*= [*Total (APP)+ Total (Control)*]/ [*Number of clusters (APP) + Number of clusters (Control)*]
- *DE* =1+*(M*-1*)*ICC;*
- *Adjusted events (APP)=Events (APP)/ DE*
- *Adjusted total (APP)=Total (APP)/ DE*
- *Adjusted events (Control)=Events (Control)/ DE*
- *Adjusted total (Control)=Total (Control)/ DE*

APP: awake prone positioning. M is the mean cluster size; ICC is the intracluster correlation coefficient, which is the between-cluster variability divided by the sum of the within-cluster and between-cluster variabilities; DE is the design effect, which is a correction factor that is used to adjust required sample size for cluster sampling.

1.3 Assessment of the certainty of evidence

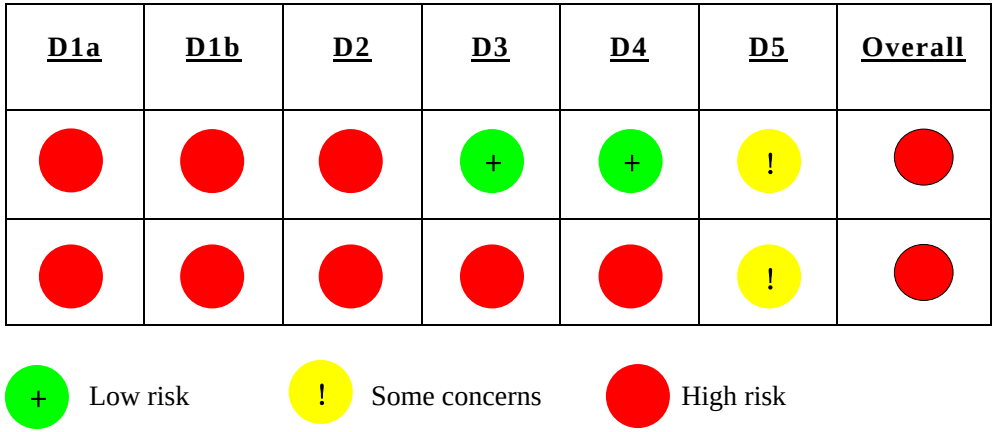
The Grading of Recommendations Assessment, Development and Evaluation (GRADE) method was used to grade the certainty of the outcomes[2].

2 Findings

2.1 Assessment of the risk of bias for cluster RCTs

The overall risk of bias was graded as high in both of the two included cluster RCTs (Kharat A, 2021[3], Taylor SP, 2021[4]) (**Figure 1**). The detailed results and reasons for the judgement of the risk of bias are presented in **Tables 1-2**.

Figure 1 Risk of bias for cluster RCTs



D1a: Randomisation process

D1b: Timing of identification or recruitment of participants

D2: Deviations from the intended interventions

D3: Missing outcome data

D4: Measurement of the outcome

D5: Selection of the reported result

Table 1 Assessment of the risk of bias for Kharat A, 2021

Signalling questions	Comments (Support for judgement)	Response
Domain 1a: Risk of bias arising from the randomization process		
1a.1 Was the allocation sequence random?	The authors reported that a computer-generated randomisation scheme was used to assign each medical ward randomly in a 1:1 ratio to either the intervention or usual care.	Y
1a.2 Was the allocation sequence concealed until clusters were enrolled and assigned to interventions?	The authors reported that the intervention was not blinded to neither physicians, nurses nor patients. Therefore, both the enrolling investigator and participants had knowledge of the forthcoming allocation.	N
1a.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Substantial differences between the actual group sizes (10 patients included in the prone position group vs 17 patients included in the control group: 17) and the intended allocation ratio (1:1).	Y
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial		
1b.1 Were all the individual participants identified and recruited (if appropriate) before randomization of clusters?	After randomisation of medical wards, four more patients were individually randomised. Therefore, some participants were recruited after randomization.	N
1b.2 If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention assigned to the cluster?	Those recruiting individuals were aware of cluster allocation before recruitment and this is likely, consciously or subconsciously, to have affected recruitment differentially between the intervention groups.	PY
1b.3 Were there baseline imbalances that suggest differential identification or recruitment of individual participants between intervention groups?	Substantial differences between the actual group sizes (10 patients included in the prone position group vs. 17 patients included in the control group) and the intended allocation ratio (1:1).	Y
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)		
2.1a Were participants aware that they were in a trial?	The enrolled patients were unblinded to the treatment. Therefore, the participants were aware that they were in a trial.	Y
2.1b. If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?	The authors reported that the physicians, nurses and enrolled patients were unblinded to the treatment. Therefore, the participants and the healthcare personnel delivering the interventions were aware of the assigned intervention during the trial.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	The authors reported that the physicians, nurses and enrolled patients were unblinded to treatment. Therefore, the participants and the healthcare personnel delivering the interventions were aware of the assigned intervention during the trial.	Y

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No information.	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The trial participants were analyzed according to the intervention they received, rather than according to the intervention to which they were assigned.	N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Half of the recruited participants were excluded after randomization, which is likely to have affected the outcome.	Y
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 3: Risk of bias due to missing outcome data		
3.1a Were data for this outcome available for all clusters that recruited participants?	The authors did not report whether any cluster had no participants.	NI
3.1b Were data for this outcome available for all, or nearly all, participants within clusters?	Data for participants did not adhere the assigned interventions were not reported.	N
3.2 If N/PN/NI to 3.1a or 3.1b: Is there evidence that the result was not biased by missing data?	The authors did not attempt to correct the bias due to missing data or conduct any sensitivity analyses.	N
3.3 If N/PN to 3.2 Could missingness in the outcome depend on its true value?	As some patients withdrew from the trial due to their health status (i.e., unable to self-prone, in end-of-life support care), missingness in the outcome may have been influenced by its true value.	PY
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	The proportions of missing outcome data differ between the groups (27 patients excluded in the prone position group vs. 8 patients excluded in the control group). Therefore, it is likely that missingness in the outcome depended on its true value	PY
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 4: Risk of bias in measurement of the outcome		
4.1 Was the method of measuring the outcome inappropriate?	The methods of measuring the outcomes were appropriate.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	The methods of measuring the outcomes were the same in all groups.	N
4.3a If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware that a trial was taking place?	In the author contribution section, it was reported the outcome assessors were also responsible for enrolment, and therefore they were aware of that a trial was taking place.	Y

4.3b If Y/PY/NI to 4.3a: Were outcome assessors aware of the intervention received by study participants?	In the author contribution section, it was reported the outcome assessors were also responsible for enrolment, therefore they were aware of the intervention received by study participants.	Y
4.4 If Y/PY/NI to 4.3b: Could assessment of the outcome have been influenced by knowledge of intervention received?	Some outcomes (e.g., need for escalating respiratory support, length of hospital stay) need subjective judgment, therefore knowledge of the assigned intervention could have influenced these outcomes.	PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	Some outcomes (e.g., need for escalating respiratory support, length of hospital stay) need subjective judgment, therefore knowledge of the assigned intervention could have influenced these outcomes.	PY
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 5: Risk of bias in selection of the reported result		
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	The researchers' pre-specified intentions were not reported in sufficient detail, and we were unable to compare the planned outcome measurements and those presented in the published report.	NI
5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible outcome measurements (e.g., scales, definitions, time points) within the outcome domain?	The researchers' pre-specified intentions were not reported in sufficient detail, and we were unable to assess this item.	NI
5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible analyses of the data?	The researchers' pre-specified intentions were not reported in sufficient detail, and we were unable to assess this item.	NI
Risk-of-bias judgement	**As per algorithm**	**Some concerns**
Overall risk of bias		**High risk**

Table 2 Assessment of the risk of bias for Taylor SP, 2021

Signalling questions	Comments	Response options
Domain 1a: Risk of bias arising from the randomization process		
1a.1 Was the allocation sequence random?	The authors reported that medical admitting teams were randomized using computer-generated random numbers.	Y
1a.2 Was the allocation sequence concealed until clusters were enrolled and assigned to interventions?	The authors reported that clinicians were unblinded to treatment allocation, and the enrolled patients were also considered unblinded. Therefore, the enrolling investigator and participants had knowledge of the forthcoming allocation.	N
1a.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Substantial differences between the actual group sizes (13 patients allocated to usual care vs. 28 patients allocated to the intervention (awake prone positioning [APP]) and the intended allocation ratio (1:1). In addition, there was a large number of baseline characteristics of clusters with statistically significant differences between the groups, which is beyond what would be expected by chance. The authors reported that there were baseline imbalances between groups (Table 2). In the as-treated population comparisons, patients without attempted prone positioning were more frequently male, Black, had chronic lung disease or heart failure, and had a history of 6 or more pack-years smoking than those with attempted prone positioning.	Y
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial		
1b.1 Were all the individual participants identified and recruited (if appropriate) before randomization of clusters?	The authors reported that eligible patients followed the care strategy to which their admitting team was randomized. Therefore, all participants were recruited after randomization.	N
1b.2 If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention assigned to the cluster?	The authors interviewed the enrolling clinicians and patients. 57% of the clinicians felt that randomizing patients to a no-prone-positioning control group was unacceptable. 67% of the patients found the position uncomfortable or intolerable in practice. These opinions are likely to have affected recruitment differentially between the groups.	Y
1b.3 Were there baseline imbalances that suggest differential identification or recruitment of individual participants between intervention groups?	There was a large number of baseline characteristics of clusters with statistically significant differences between the groups, which is beyond what would be expected by chance.	Y
Risk-of-bias judgement	**As per algorithm**	**High risk**

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)		
2.1a Were participants aware that they were in a trial?	The enrolled patients were unblinded to treatment. The authors collected qualitative data from semi-structured interviews with patients in the APP treatment arm. Therefore, participants were aware that they were in a trial.	Y
2.1b. If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?	The authors reported that the clinicians and enrolled patients were unblinded to treatment. Therefore, participants and the personnel delivering the interventions were aware of the assigned intervention during the trial.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	The authors reported that the clinicians and enrolled patients were unblinded to treatment. Therefore, participants and the personnel delivering the interventions were aware of the assigned intervention during the trial.	Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	The authors observed diffusion of prone positioning into the usual care (UC) group, reinforced by interview data whereby many clinicians revealed that prone positioning was already considered UC for nonincubated patients in their setting. Therefore, deviations from the UC group could be considered to have arisen.	Y
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	Diffusion of prone positioning into the usual care resulted in imbalance between groups and further had an impact on the intervention effect estimate.	Y
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	Diffusion of prone positioning into the usual care resulted in imbalance between groups and further had an impact on the intervention effect estimate.	N
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The authors explored changes in the defined endpoints by using intention-to-treat analysis.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA.	NA
Risk-of-bias judgement	**As per algorithm**	**High risk**
Domain 3: Risk of bias due to missing outcome data		
3.1a Were data for this outcome available for all clusters that recruited participants?	Nearly all data were available.	Y
3.1b Were data for this outcome available for all, or nearly all, participants within clusters?	Nearly all data were available.	Y
3.2 If N/PN/NI to 3.1a or 3.1b: Is there evidence that the result was not biased by missing data?	NA	NA
3.3 If N/PN to 3.2 Could missingness in the outcome depend on its true value?	NA	NA

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA
Risk-of-bias judgement	**As per algorithm**	**Low risk**
Domain 4: Risk of bias in measurement of the outcome		
4.1 Was the method of measuring the outcome inappropriate?	The methods of measuring the outcomes were appropriate.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	The methods of measuring the outcomes were the same between the groups.	N
4.3a If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware that a trial was taking place?	The authors claimed that clinical and safety outcomes were collected from the electronic health record by study investigators blinded to treatment assignment.	N
4.3b If Y/PY/NI to 4.3a: Were outcome assessors aware of the intervention received by study participants?	NA.	NA
4.4 If Y/PY/NI to 4.3b: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA.	NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA.	NA
Risk-of-bias judgement	**As per algorithm**	**Low risk**
Domain 5: Risk of bias in selection of the reported result		
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Analysis intentions are not available.	NI
5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible outcome measurements (e.g., scales, definitions, time points) within the outcome domain?	Analysis intentions are not available.	NI
5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible analyses of the data?	Analysis intentions are not available.	NI
Risk-of-bias judgement	**As per algorithm**	**Some concerns**
Overall risk of bias		**High risk**

2.2 Estimates of the outcomes adjusted for design effect (cluster RCT design)

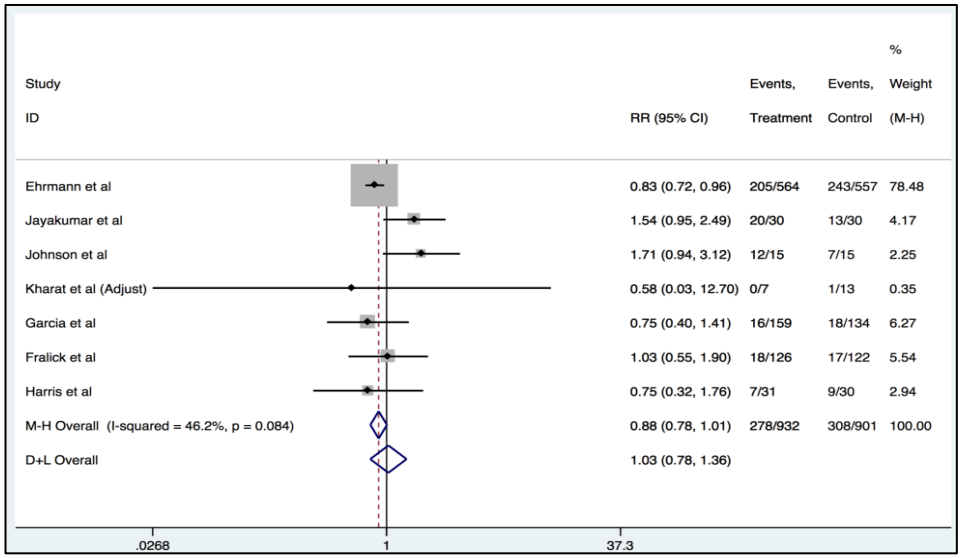
For the primary outcome (intubation), there were no events in neither of the two cluster RCTs and the data from the two cluster RCTs were thus not included in the data synthesis. Therefore, the result of the primary outcome was not affected and remained unchanged (**Table 3**). The results for the need for escalating respiratory support (random effects model: RR=1.03, 95%CI 0.78 to 1.36), ICU admission (random effects model: RR=0.80, 95%CI 0.52 to 1.22), and length of hospital stay (random effects model: MD=0.55 days, 95%CI -0.52 to 1.62) differed from the results reported by Li et al (**Table 3, Figures 2-4**).

Table 3 The analysis adjusted for clustering of the included cluster randomized controlled trials for each outcome

Outcome	Study ID	Number of clusters (APP)	Events (APP)	Total (APP)	Number of clusters (Control)	Events (Control)	Total (Control)	ICC	M	Design effect	Adjusted events (APP)	Adjusted total (APP)	Adjusted events (Control)	Adjusted total (Control)
Intubation	Kharat et al	3	0	10	3	0	17	0.1	4.5	1.35	0	7	0	13
	Taylor et al	3	0	27	2	0	13	0.11	8	1.77	0	15	0	7
All-cause mortality	Kharat et al	3	0	10	3	0	17	0.1	4.5	1.35	0	7	0	13
	Taylor et al	3	0	27	2	0	13	0.11	8	1.77	0	15	0	7
Need for escalating respiratory support	Kharat et al	3	0	10	3	1	17	0.1	4.5	1.35	0	7	1	13
ICU admission	Kharat et al	3	0	10	3	0	17	0.1	4.5	1.35	0	7	0	13
	Taylor et al	3	8	27	2	6	13	0.11	8	1.77	5	15	3	7
Hospital length of stay	Kharat et al	3	NA	10	3	NA	17	0.1	4.5	1.35	NA	7	NA	13
	Taylor et al	3	NA	27	2	NA	13	0.11	8	1.77	NA	15	NA	7

Note: M is the average cluster size. APP: awake prone positioning; ICC: intracluster correlation coefficient; NA: Not applicable.

Figure 2 Forest plots for the need for escalating respiratory support： A) adjusted for design effect, B) reported by Li et al



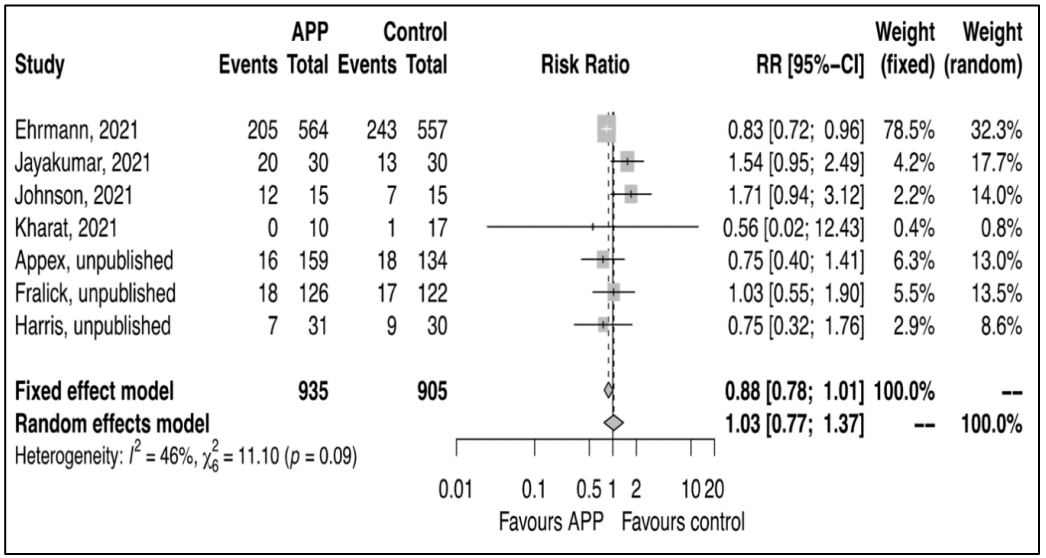
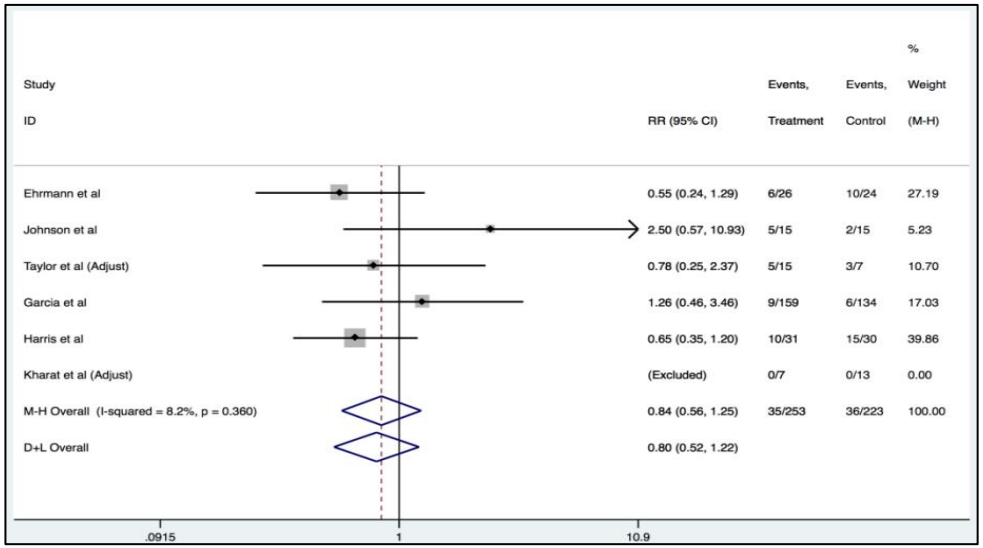


Figure 2A

Figure 2B

Figure 3 Forest plots for ICU admission: A) adjusted for design effect, B) reported by Li et al



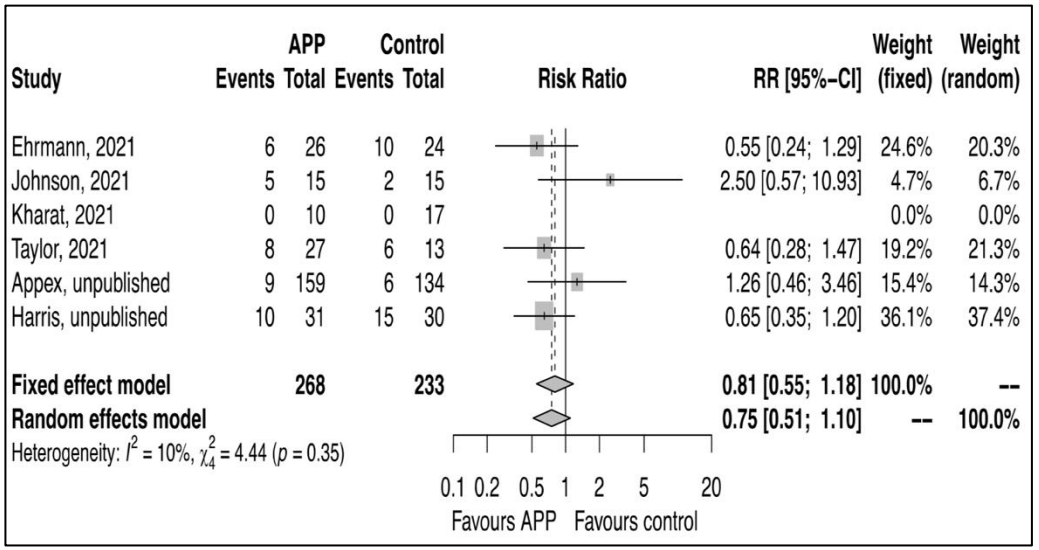
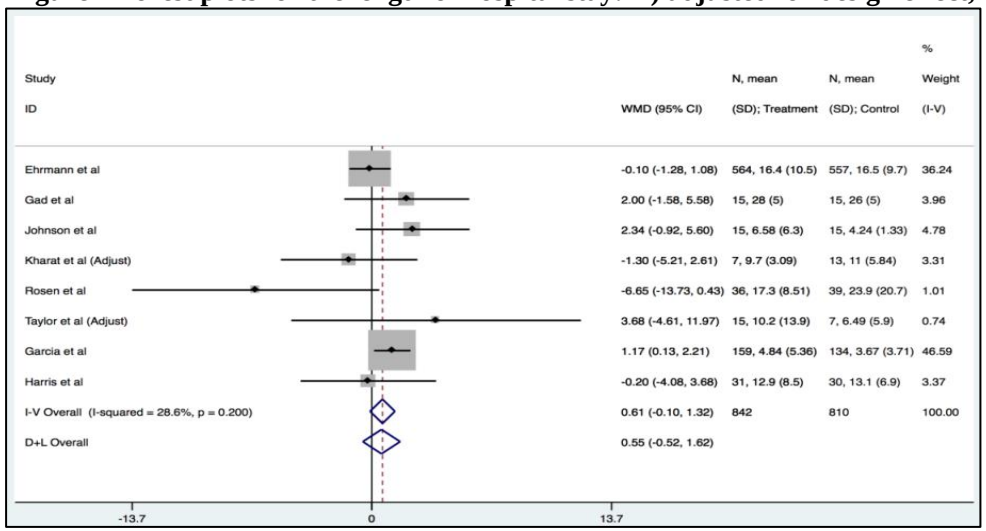


Figure 3A

Figure 3B

Figure 4 Forest plots for the length of hospital stay: A) adjusted for design effect, B) reported by Li et al



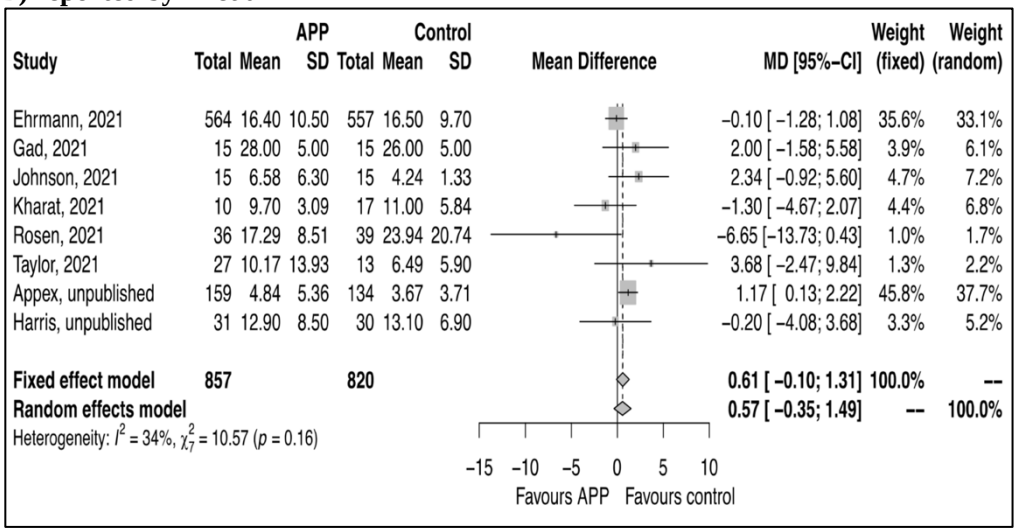


Figure 4A

Figure 4B

2.3 Assessment of the certainty of evidence

Therefore, the certainty of the evidence on all outcomes should be downgraded one level from those reported by Li et al because of the serious risk of bias (e.g., the certainty of the evidence on intubation should be "moderate" instead of "high"). The revised assessment for the certainty of the evidence and risk of bias are presented in **Table 4**.

Table 4 Grading of recommendations, assessment, development and evaluations (GRADE)

Outcome	No of studies	Study design	No of patients		Certainty assessment					No of patients		Effect (Random effects model)		Certainty
			APP	Control	Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	APP	Control	Relative risk (95% CI)	Absolute effect (95% CI)	
Risk of intubation	10	RCT	1013	972	Serious[a]	Low[b]	Low[h]	Low	Low[j]	216/976 (22.1%)	255/942 (27.1%)	0.84 (0.72-0.97)	-	⨁⨁⨁◯ Moderate
Subgroup: Advanced respiratory support	3	RCT	605	604	Serious[a]	Low[c]	Low[h]	Low	-	198/605 (32.7%)	237/604 (39.2%)	0.83 (0.71-0.97)	-	⨁⨁⨁◯ Moderate
Subgroup: Conventional oxygen therapy	8	RCT	405	368	Serious[a]	High[d]	Low[h]	Low	-	16/368 (4.3%)	18/338 (5.3%)	0.87 (0.45-1.69)	-	⨁⨁◯◯ Low
Subgroup: ICU	3	RCT	583	578	Serious[a]	Low[c]	Low[h]	Low	-	189/583 (32.4%)	226/578 (39.1%)	0.83 (0.71-0.97)	-	⨁⨁⨁◯ Moderate
Subgroup: Non ICU	7	RCT	394	355	Serious[a]	High[d]	Low[h]	Low	-	15/357 (4.2%)	16/325 (4.9%)	0.88 (0.44-1.76)	-	⨁⨁◯◯ Low
Mortality	10	RCT	1013	972	Serious[a]	High[d]	Low[h]	Low	High[k]	135/976 (13.8%)	143/942 (15.2%)	1.0 (0.70-1.44)	-	⨁◯◯◯ Very low
Subgroup: Advanced respiratory support	3	RCT	605	604	Serious[a]	High[d]	Moderate[i]	Low	-	124/605 (20.5%)	135/604 (22.4%)	1.23 (0.54-2.80)	-	⨁◯◯◯ Very low
Subgroup: Conventional oxygen therapy	8	RCT	405	368	Serious[a]	High[d]	Low[h]	Low	-	10/342 (2.9%)	8/316 (2.5%)	1.14 (0.47-2.75)	-	⨁◯◯◯ Very low
Subgroup: ICU	3	RCT	583	578	Serious[a]	High[e]	Low[h]	Low	-	116/583 (19.9%)	127/578 (22.0%)	0.90 (0.72-1.13)	-	⨁◯◯◯ Very low
Subgroup: Non ICU	7	RCT	394	355	Serious[a]	Low[f]	Low[h]	Low	-	13/357 (3.6%)	13/325 (4.0%)	0.81 (0.41-1.59)	-	⨁⨁◯◯ Low
Need for escalation of respiratory support	7	RCT	935	905	Serious[a]	High[d]	Moderate[i]	Low	Low[j]	278/935 (29.7%)	308/905 (34.0%)	1.03 (0.77-1.37)	-	⨁◯◯◯ Very low
Need for ICU admission	6	RCT	268	233	Serious[a]	Moderate[g]	Low[h]	Low	Low[k]	38/258 (14.7%)	39/216 (18.1%)	0.75 (0.51-1.10)	-	⨁⨁⨁◯ Moderate
ICU length of stay	5	RCT	472	508	Serious[a]	High[e]	Low[h]	Low	Low[j]	472	508	-	0.08 days longer (-0.89-1.05)	⨁◯◯◯ Very low
Hospital length of stay	8	RCT	857	820	Serious[a]	High[e]	Moderate[i]	Low	Low[j]	857	820	-	0.57 days longer (-0.35-1.49)	⨁◯◯◯ Very low

a. In all eight individual RCTs, the overall risk of bias was graded as high due to lack of blinding according to the Cochrane criteria. In the two cluster RCTs, the risks of bias due to randomisation process, timing of identification or recruitment of participant, and deviations from the intended interventions were graded as high. Therefore, the overall risk of bias was serious in all trials.

b. Although the 95% CI of relative risk was close to a relative risk of 1.0 (no effect), the largest plausible effect suggested that APP might reduce the relative risk of intubation by as much as 28% especially when considering the overall risk of intubation of 40% or more in hypoxemic patients with COVID-19. In addition, trial sequential analysis supported the true positive conclusion by reaching the optimal information size.

c. Although the 95% CI of relative risk was close to a relative risk of 1.0 (no effect), the largest plausible effect suggested that APP might reduce the relative risk of intubation by as much as 29% especially when considering the overall risk of intubation of 40% or more in hypoxemic patients with COVID-19. In addition, trial sequential analysis did not indicated futility although the optimal information size was not reached but very close already.

d. The 95% CI of relative risk was wide and overlapped a relative risk of 1.0 (no effect). Trial sequential analysis indicated that the optimal information size was not reached.

e. The 95% CI of relative risk overlapped a relative risk of 1.0 (no effect). Trial sequential analysis indicated that the optimal information size was not reached.

f. Although the 95% CI of relative risk overlapped a relative risk of 1.0 (no effect), trial sequential analysis indicated that the optimal information size was reached.

g. The 95% CI of relative risk overlapped a relative risk of 1.0 (no effect). Although the optimal information size was not reached, but trial sequential analysis indicated futility in the pooled effect estimate. h. Confidence intervals of each study overlapped and no statistical heterogeneity was found.

i. I^2 = 32% although heterogeneity test showed p-value > 0.05.

j. Egger's test showed symmetry.

k. Egger's test showed symmetry.

APP, awake prone positioning; CI, confidence interval; ICU, intensive care unit; RCT, randomized controlled trial.

References

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