Evaluacion comparativa de cuatro metodos de fijacion de tubo orotraqueal: resultados preliminares [Comparative evaluation of four methods of an endotracheal tube holder: preliminary results]
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Four types of endotracheal tube holders (ETH) were studied. These were sticking plaster, gauze bandage, Haid and Secure-Easy.

Type of intervention
Device.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included patients older than 18 years of age, who were admitted to the ICU and required intubation for more than 24 hours. Patients who did not agree to cut their beards or moustaches for the application of the study device were excluded from the study population, as were those presenting with facial, cranial and/or cerebral trauma.

Setting
The study was set in the ICU of a teaching hospital. The economic study was carried out at the Hospital Universitario de Canarias in Santa Cruz de Tenerife, Spain.

Dates to which data relate
Neither the dates nor the price year were reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
A sample of 68 patients consecutively admitted to the study hospital was included in the study. There were 14 patients (mean age 65.93 years) in the sticking plaster group, 16 (mean age 61.81) in the gauze bandage group, 21 (mean age 63.53) in the Haid group and 17 (mean age 63.97) in the Secure-Easy group. The proportion of men in each group were, respectively, 57.1% (sticking plaster), 56.3% (gauze bandage), 66.7% (Haid) and 64.8% (Secure-Easy). The 68
patients formed part of the wider group of 101 eligible patients who were admitted during the study period. The remaining patients were not included in the final sample because the final intubation time was less than the 24 hours required for inclusion in the trial. Of the patients excluded from the initial sample (30.6), 12 were in the sticking plaster group, 9 in the gauze bandage group, 4 in the Haid group and 5 in the Secure-Easy group. It appears that the excluded patients were younger than those who remained in the study. Power calculations indicated that, for the long-term study, a sample of 188 was required to detect statistically significant differences in the outcome measures. However, no power calculations were performed for the present preliminary study.

**Study design**
This was an open, parallel-group, randomised controlled trial. The method of randomisation was not reported. Patients were admitted to a single centre, the ICU of the Hospital Universitario de Canarias in Santa Cruz de Tenerife. The length of follow-up was 6 months and no loss to follow-up was reported.

**Analysis of effectiveness**
The primary health outcomes used in the analysis were objective and subjective measures. The objective measures were time to the first skin and mucose membrane lesion, and the severity, number and localisation of lesions. These were assessed using the Norton scale, ranging from 0 (no ulcer) to 3 (presence of ulcer). The subjective measures were the ease of collocation of the ETHs and patient comfort, as perceived by the patient or by the nurse. These were assessed using the Likert scale, ranging from 0 (minimum ease or comfort level) to 5 (maxim ease or comfort). Safety was assessed in the long-term study, but an assessment was not available in the preliminary study. The basis of the analysis of the clinical study was not stated. The study groups were perfectly comparable at baseline in terms of gender, age, type of pathology and length of intubation.

**Effectiveness results**
Among the objective measures, the time to the first skin and mucose membrane lesion was 41.36 (+/- 4.06) hours in the sticking plaster group, 93.85 (+/- 21.41) in the gauze bandage group, 194.47 (+/- 27.52) in the Haid group, and 53.01 (+/- 6.21) in the Secure-Easy group. Thus, lesion-free time was higher with Haid, followed by gauze bandage, Secure-Easy and sticking plaster. These differences were statistically significant.

Haid performed significantly better for both the severity and the number of lesions, followed by gauze bandage, Secure-Easy and sticking plaster.

No statistically significant difference was found in terms of lesion localisation.

Among the subjective measures, the scores for ease of collocation of the ETHs were 2.1957 (+/- 0.8042) for sticking plaster, 3.3773 (+/- 0.7472) for gauze bandage, 4.6767 (+/- 0.2891) for Haid, and 1.6446 (+/- 0.6105) for Secure-Easy.

The scores for patient comfort, as perceived by the nurse, were 1.9971 (+/- 0.9156) for sticking plaster, 3.0669 (+/- 0.6261) for gauze bandage, 4.1445 (+/- 0.5298) for Haid, and 1.8498 (+/- 0.7422) for Secure-Easy.

The scores for patient comfort, as perceived by the patient, were 1.4586 (+/- 0.4084) for sticking plaster, 2.5600 (+/- 0.3628) for gauze bandage, 3.7985 (+/- 0.2196) for Haid, and 2.6757 (+/- 0.5629) for Secure-Easy.

Most of the differences in subjective measures reached statistical significance.

**Clinical conclusions**
Haid was generally more effective than the remaining techniques in terms of many outcome measures. Sticking plaster was the least effective, and the authors stated that its use was interrupted during the study. Surprisingly, nurses found the Secure-Easy device to be difficult to use, and it led to both a substantial number of lesions and a shorter lesion-free time. Finally, the gauze bandage method performed well in comparison with both sticking plaster and Secure-Easy, but was less effective than Haid.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore carried out.

Direct costs
The costs included in the analysis from the perspective of the hospital were for the personnel, device and the time required to arrange the ETHs. The quantities of resources used were reported. The unit costs were not given. Discounting was irrelevant since the costs were incurred over 6 months. Resource use was estimated alongside the effectiveness study, while the costs were based on actual data derived from the Cost Department of the study hospital. The price year was not reported.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were included.

Currency
Spanish pesetas (Pta).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The daily costs were Pta 1,887 with sticking plaster, Pta 1,902 with gauze bandage, Pta 1,264 with Haid and Pta 4,134 with Secure-Easy.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The Haid device, which was designed by the authors themselves, was highly effective in comparison with the other techniques and its costs were the lowest. Thus, it appears to be the best endotracheal tube holder (ETH) in patients admitted to the intensive care unit (ICU). An important conclusion was that the sticking plaster was no longer used after the high incidence and severity of lesions reported.

CRD COMMENTARY - Selection of comparators
The authors discussed in detail the choice of the comparators. Gauze bandage was the technique of choice in the study hospital, while sticking plaster was widely used in other hospitals in the same geographic area as that of the study hospital. Secure-Easy was the most common method in the literature, and Haid was the technique designed by the authors of the present study. You should decide whether they are widely used techniques in your own setting.
Validity of estimate of measure of effectiveness
The internal validity was high since the effectiveness evidence came from a randomised controlled trial, which was appropriate for the study question. The study groups were comparable at baseline. The study sample was representative of the whole study population of patients eligible for the four interventions. The authors reported the demographic data of patients who were first enrolled in the study, but were then excluded from the initial study sample on account of their short stay in the ICU. These issues enhanced the internal validity of the analysis. However, neither the method of randomisation nor the basis of the analysis of the clinical study (intention to treat or treatment completers only) were reported.

Validity of estimate of measure of benefit
A cost-consequences analysis was conducted.

Validity of estimate of costs
It appears that all the costs relevant to the perspective adopted in the study have been included in the analysis. Neither the unit costs nor the price year were reported, making it difficult to replicate the study in other contexts and under different conditions. The costs were treated deterministically and sensitivity analyses were not performed. The cost estimates were specific to the study setting. The quantities of resources were reported as average values plus or minus the standard deviations.

Other issues
The authors did not compare their results with those from other studies. They also did not address the issue of the generalisability of the conclusions of their analysis to other settings. Sensitivity analyses were not performed, thus the external validity of the analysis was low.

Implications of the study
The Haid should be the device of choice for the management of patients admitted to ICU. The authors suggested that further studies should be carried out to provide more evidence on the different ETHs.

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