## Yuan, 2020

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| **Bibliographic Reference** | Yuan, D.; Zhang, J.; Wang, X.; Chen, S.; Wang, Y.; Intensified Oral Hygiene Care in Stroke-Associated Pneumonia: A Pilot Single-Blind Randomized Controlled Trial; Inquiry; 2020; vol. 57; 46958020968777 |

**Study details**

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| **Secondary publication of another included study- see primary study for details** | No additional information. |
| **Other publications associated with this study included in review** | No additional information. |
| **Trial name / registration number** | Chinese Clinical Trial Registry: ChiCTR-IPR-17013403. |
| **Study type** | Randomised controlled trial (RCT) |
| **Study location** | China. |
| **Study setting** | One neurological intensive care unit in a hospital in China. |
| **Study dates** | June 2017 to September 2018. |
| **Sources of funding** | This work was supported by the Beijing Science and Technology Committee (grant number Z151100004015041) and the Beijing Stomatological Hospital Subject Construction Fund (grant number 16-09-20). |
| **Inclusion criteria** | A clinical diagnosis of acute stroke; admission within 24 hours after stroke onset; age 18 years or older. |
| **Exclusion criteria** | Diagnosed with pneumonia or showed clinical signs of infection on admission; required mechanical ventilation; were prescribed antibiotics or immunosuppressive agents within the preceding 2 months; were unable to receive oral care within 12 hours of admission; had an allergy to chlorhexidine; were pregnant. |

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| **Recruitment / selection of participants** | No additional information. |
| **Intervention(s)** | Intensified oral hygiene interventions (3 times a day) N=56<br><br>Routine oral hygiene care for a duration of 7 days. Cognitively intact participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants lacking the ability to perform oral care, including all participants in the intensive care unit, received oral swabbing with saline (2-minute duration, twice daily). Intensified oral hygiene interventions in addition to oral self-care (or instead of routine saline swabbing), all teeth and oral soft tissues (including the gingiva, vestibule, buccal mucosa, floor of the mouth, tongue dorsum, and pharynx oralis), were swabbed with 0.12% chlorhexidine digluconate mouth wash (5-minute duration, 3 times daily). All interventions were performed by nurses who had been trained by a dental professional prior to the commencement of the study. |
| **Comparator** | Usual care N=57<br><br>Routine oral hygiene care for a duration of 7 days. Cognitively intact participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants lacking the ability to perform oral care, including all participants in the intensive care unit, received oral swabbing with saline (2-minute duration, twice daily). |
| **Number of participants** | 113 |
| **Duration of follow-up** | 7 days |
| **Additional comments** | No additional information |
| **Subgroup 1: Severity (as stated by category or as** | Moderate (or NIHSS 5-14) |

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| **measured by NIHSS scale)** | |
| **Subgroup 2: Type of stroke (using the Bamford scale)** | Not stated/unclear |
| **Subgroup 3: Dysphagia at baseline** | Not stated/unclear |
| **Subgroup 4: Type of intervention** | Oral swabbing for secretions |
| **Subgroup 5: People who are nil-by-mouth at baseline** | Not stated/unclear |
| **Subgroup analysis - further details** | Severity: Given median and interquartile range values. People were between mild and severe, with the majority being of moderate severity.<br><br>Type of stroke: Discusses ischaemic, intracerebral haemorrhage and subarachnoid haemorrhage (majority ischaemic). |

**Study arms**

***Intensified oral hygiene interventions (3 times a day) (N = 56)***

Routine oral hygiene care for a duration of 7 days. Cognitively intact participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants lacking the ability to perform oral care, including all participants in the intensive care unit, received oral swabbing with saline (2-minute duration, twice daily). Intensified oral hygiene interventions in addition to oral self-care (or instead of routine saline swabbing), all teeth and oral soft tissues (including the gingiva, vestibule, buccal mucosa,

floor of the mouth, tongue dorsum, and pharynx oralis), were swabbed with 0.12% chlorhexidine digluconate mouth wash (5-minute duration, 3 times daily). All interventions were performed by nurses who had been trained by a dental professional prior to the commencement of the study.

***Usual care (N = 57)***

Routine oral hygiene care for a duration of 7 days. Cognitively intact participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants with adequate manual dexterity and unimpaired mouth opening capacity were asked to perform oral care by themselves, with or without the help of a nursing assistant. Those participants lacking the ability to perform oral care, including all participants in the intensive care unit, received oral swabbing with saline (2-minute duration, twice daily).

**Characteristics**

***Arm-level characteristics***

| Characteristic | Intensified oral hygiene interventions (3 times a day) (N = 56) | Usual care (N = 57) |
|---|---|---|
| **% Female**<br>Baseline characteristics only reported in 43 in the intervention group, and 41 in the control group.<br><br>Sample size | n = 19 ; % = 44.2 | n = 14 ; % = 34.1 |
| **Mean age (SD)**<br><br>Mean (SD) | 57.1 (13.4) | 60.3 (13.7) |
| **Ethnicity**<br><br>Nominal | NR | NR |

| Characteristic | Intensified oral hygiene interventions (3 times a day) (N = 56) | Usual care (N = 57) |
|---|---|---|
| **Comorbidities**<br><br>Nominal | NR | NR |
| **Severity**<br><br>Median (IQR) | 9 (1 to 18) | 10 (1.5 to 17) |
| **Ischaemic**<br><br>Nominal | 25 | 25 |
| **Intracerebral haemorrhage**<br><br>Nominal | 8 | 9 |
| **Subarachnoid haemorrhage**<br><br>Nominal | 10 | 7 |
| **Dysphagia at baseline**<br><br>Nominal | NR | NR |
| **People who are nil-by-mouth at baseline**<br><br>Nominal | NR | NR |
| **Stroke more than once**<br>Baseline characteristics only reported in 43 in the intervention group, and 41 in the control group.<br><br>Nominal | 7 | 11 |

**Outcomes**

***Study timepoints***

- Baseline
- 7 day (This group will be included in the ≤3 months.)

***Oral hygiene intervention (3 times a day) compared to usual care - dichotomous outcomes***

| Outcome | Intensified oral hygiene interventions (3 times a day), Baseline, N = 56 | Intensified oral hygiene interventions (3 times a day), 7 day, N = 43 | Usual care, Baseline, N = 57 | Usual care, 7 day, N = 41 |
|---|---|---|---|---|
| **Mortality**<br><br>Nominal | NR | 2 | NR | 4 |
| **Occurence of pneumonia**<br>Intervention: 5 Staphylococcus aureus, 3 Klebsiella pneumoniae, 1 Candida albicans. Control: 5 Staphylococcus aureus, 6 Klebsiella pneumoniae, 4 Acinetobacter baumannii, 1 Candida albicans, 1 Psuedomonas aeruginosa.<br><br>Nominal | NR | 9 | NR | 17 |

Mortality - Polarity - Lower values are better

Occurence of pneumonia - Polarity - Lower values are better

***Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT***

***Oralhygieneintervention(3timesaday)comparedtousualcare-dichotomousoutcomes-Mortality-Nominal-Intensified oral hygiene interventions (3 times a day)-Usual care-t7***

| Section | Question | Answer |
|---|---|---|
| Overall bias and Directness | Risk of bias judgement | High |
| Overall bias and Directness | Overall Directness | Directly applicable |

***Oralhygieneintervention(3timesaday)comparedtousualcare-dichotomousoutcomes-Occurenceofpneumonia-Nominal-Intensified oral hygiene interventions (3 times a day)-Usual care-t7***

| Section | Question | Answer |
|---|---|---|
| Overall bias and Directness | Risk of bias judgement | High |
| Overall bias and Directness | Overall Directness | Directly applicable |