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Research Article

Relative and bedside nurse assessment of comfort and communication during propofol, dexmedetomidine, or clonidine-based sedation: pre-planned analysis within the A2B RCT

Timothy S Walsh^{1*}, Richard A Parker², Leanne M Aitken³, Cathrine A McKenzie⁴, Robert Glen⁵, Christopher J Weir² and the A2B Trial Investigators Group

¹Usher Institute, The University of Edinburgh, Edinburgh, UK

²Edinburgh Clinical Trials Unit, Usher Institute, The University of Edinburgh, Edinburgh, UK

³City St George's, University of London, London, UK

⁴NIHR Southampton Biomedical Research Centre, Perioperative and Critical Care Theme, University of Southampton, Southampton, UK

⁵Lay Member, Edinburgh, UK

*Corresponding author timothy.walsh@ed.ac.uk

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Abstract

Background: Optimising comfort and ability to communicate for mechanically ventilated intensive care unit patients is a priority for clinicians, intensive care unit patients and their relatives. Current usual care is propofol-based sedation plus an opioid analgesic. The alpha2-agonists dexmedetomidine and clonidine are potential alternative sedatives.

Objective(s): To explore whether nurses and relatives perceive patients sedated with dexmedetomidine and/or clonidine appear more awake, comfortable and co-operative than patients receiving only propofol-based sedation.

Design and methods: Substudy within an open-label, three-arm trial.

Setting and participants: Forty-one intensive care units in the United Kingdom. One thousand four hundred and thirty-seven adults receiving propofol ± opioid for sedation-analgesia within 48 hours of starting mechanical ventilation, expected to require ≥ 48 total hours of mechanical ventilation.

Interventions: Light sedation was targeted in all patients unless clinicians requested deeper sedation. In intervention groups, algorithms promoted alpha2-agonist up-titration and propofol down-titration, followed by sedation primarily with allocated alpha2-agonist. Usual care was propofol-based sedation. Intervention continued until patients were successfully extubated (primary outcome), or other pre-defined end points.

Outcomes For each 12-hour care period, nurses responded to two 'yes/no' questions: *is the patient able to communicate pain?* *Is the patient able to co-operate with care?* When the patients' personal legal representative visited, they were asked for 'yes/no' responses to three questions: *does the patient appear awake?* *Does the patient appear comfortable?* *Does the visitor feel they can communicate with the patient?*

Intervention versus propofol group responses were compared fitting a generalised linear mixed model, with results expressed as odds ratios (95% confidence intervals); odds ratios > 1 indicated greater probability of a 'yes' response.

Results: Nurse responses were available for > 90% of trial patients [mean (standard deviation) 12 (12) care periods per patient]. Comparing dexmedetomidine versus propofol groups, the odds ratio for a 'yes' response to '*communicate pain*' was 1.38 (95% confidence interval 1.08 to 1.75), and for clonidine versus propofol, it was 1.13 (0.89 to 1.43). For '*co-operate with care*' comparing dexmedetomidine versus propofol groups, the odds ratio was 1.14 (95% confidence interval 0.98 to 1.32), and for clonidine versus propofol, it was 0.96 (95% confidence interval 0.83 to 1.12). Relative responses were available for 32–34% of trial patients across groups [mean (standard deviation) 3 (3) days per patient]. For the '*appear awake*' question, the dexmedetomidine versus propofol group odds ratio was 1.48 (95% confidence interval 1.04 to 2.10), and for clonidine versus propofol, it was 1.35 (95% confidence interval 0.95 to 1.91). For '*appear comfortable*', the dexmedetomidine versus propofol group odds ratio was 0.64 (95% confidence interval 0.38

to 1.09), and for clonidine versus propofol, it was 0.78 (95% confidence interval 0.45 to 1.34). For the '*feel they can communicate*' comparison, the dexmedetomidine versus propofol group odds ratio was 1.00 (95% confidence interval 0.68 to 1.47), and for clonidine versus propofol, it was 1.05 (95% confidence interval 0.71 to 1.54).

Limitations: Interventions were unblinded, with risk of bias; missing data may not have been at random.

Conclusions: Nurses perceived patients receiving dexmedetomidine-based sedation could better communicate pain than with propofol-based sedation, and relatives perceived patients appeared more awake. No differences for the other questions were found, or for the clonidine versus propofol comparisons, although some uncertainty remains due to the wide confidence intervals.

Future work: Additional mixed-methods research of sedation quality with different agents from staff and relative perspectives.

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Background

Achieving comfort, analgesia and enabling communication with intensive care unit (ICU) patients is a goal of optimum sedation.¹ The views of staff and relatives regarding the overall comfort of patients and their ability to co-operate with care have not previously been studied in trials of ICU sedation. Protocols to guide pain, agitation and delirium management typically use validated rating scales completed by bedside staff, such as the Richmond Agitation–Sedation Scale (RASS),² Confusion Assessment Method for the ICU (CAM-ICU)³ and Behavioural Pain Scale.⁴ These categorise patient status in order to prompt changes in treatment rather than reflecting the views of staff and relatives. Many patients recall pain, anxiety and discomfort following ICU discharge, with a high prevalence of frightening memories and long-term psychological morbidity.^{5,6} The need for more holistic approaches to ensuring patient comfort has been highlighted by consensus groups and guidelines.^{1,7}

The Alpha 2 agonists for sedation to produce Better outcomes from critical illness (A2B) trial was a randomised trial comparing ICU sedation based on propofol, dexmedetomidine or clonidine for patients expected to require more than 48 hours of mechanical ventilation (MV).⁸ The main results of the trial have been reported elsewhere.⁹ Briefly, neither dexmedetomidine- nor clonidine-based sedation decreased the primary outcome of time to successful extubation. Among secondary outcomes, neither alpha2-agonist improved rates of delirium, unnecessary deep sedation or pain behaviours, but both were associated with higher rates of patient agitation. Within the trial, we undertook a pre-planned exploration of the views of bedside nurses and relatives visiting patients regarding their perceptions of patient comfort and communication while receiving sedation with the allocated trial interventions. We hypothesised that nurses and relatives would perceive that the patients sedated with dexmedetomidine and/or clonidine were

more awake, comfortable and co-operative than patients receiving only propofol-based sedation. We report here the results of this analysis.

Methods

The A2B trial overview

The A2B trial protocol has been published.⁸ Briefly, eligible patients were receiving MV in the ICU, aged ≥ 18 years, and were within 48 hours of starting MV and sedated with propofol. At randomisation, they were expected to require a further 24 hours of MV and a total of ≥ 48 hours. Exclusion criteria included: acute brain injury, neuromuscular paralysis, bradycardia < 50 beats per minute for ≥ 60 minutes and patients not expected to survive a further 24 hours. Randomisation used a remote web-based system, allocating in a 1 : 1 : 1 ratio to the three groups using permuted blocks stratified by centre. Intervention group patients commenced intravenous infusion of open-label drug using a weight-based dose regimen within 2 hours post randomisation. Bedside nurses used group-specific algorithms to up-titrate alpha2-agonist and down-titrate propofol to transition patients to receive the allocated alpha2-agonist, with the aim of alpha2-agonist-based sedation, supplemented with propofol if required. Usual care (UC) was propofol-based sedation without specific dose-guidance. For all groups, bedside algorithms indicated a sedation target RASS score of -2 to $+1$ [range: -5 (unresponsive) to $+4$ (combative)], unless responsible clinicians requested deeper sedation for therapeutic reasons. The choice and dosing of opioid for analgesia were determined by the clinical team according to UC and clinical judgement. For the majority of patients, this was either fentanyl or alfentanil according to local prescribing policies. Other sedatives were discouraged and recorded as 'rescue medications', if required. Interventions continued until the patient was successfully extubated,

died during MV, was transferred before extubation to a non-participating ICU or until the end of 28 days of MV.

Ethical approval

The A2B trial received ethical approval from the Scotland A Research Ethics Committee (REC) (reference 18/SS/0085) on 21 August 2018. This exploratory analysis was part of the main protocol, and the relevant outcomes were included in the pre-specified statistical analysis plan.¹⁰ Ethical approval allowed any clinical nurse providing care during the trial to participate without additional written consent. For relatives, ethical approval was provided for the Personal Legal Representative (PerLegR), who had provided written consent for participation in the trial, usually the next-of-kin, to be approached to provide responses when they visited the patient. Assessments of relatives' views were, therefore, always the same individual for each patient. As the A2B trial included a deferred consent model when relatives were unavailable 2 hours after confirming eligibility, the PerLegR might have provided consent after starting the intervention.

Assessment and data collection

All patients were assessed while receiving their allocated sedation intervention from randomisation until either primary outcome (successful extubation), death prior to primary outcome, transfer to another ICU before extubation or 28 days post randomisation without achieving the primary outcome. Caring nurse data collection was based on 12-hour nursing shifts. The nurse was asked to complete a 'nursing shift' form that included: whether a clinical request for deep sedation was made; regular RASS scores (suggested 4 hourly); a CAM-ICU score (once per shift); and assessments of two behavioural pain ratings based on ventilator compliance and upper limb movement. These outcomes contributed to outcomes reported for the main trial publication. At the end of each nursing care period ('day shift' and 'night shift'), nurses were also asked to respond to two binary 'yes/no' questions about their view of the patient's comfort and co-operation during that shift, namely: *is the patient able to communicate pain?* And, *is the patient able to co-operate with care?*

For relative assessments, when the PerLegR visited and agreed to provide an opinion, they were asked to provide the caring nurse with a binary 'yes/no' response to three questions, namely: *does the patient appear awake to the visitor?* *Does the patient appear comfortable to the visitor?* And, *does the visitor feel they can communicate with the patient?* The bedside nurse recorded responses on the daily shift forms. Data recorded on daily shift forms were entered onto the trial database by local research staff.

Patient and public involvement

The decision to include the views of visiting relatives was strongly supported by a patient and public involvement (PPI) group who helped develop the trial funding proposal and subsequently contributed to protocol design. The choice and wording of questions put to relatives was informed by a group of ICU survivors and their relatives. A lay co-applicant, Bob Glen, was part of the Trial Management Group throughout the trial and reviewed information materials. An independent PPI representative was a member of the Trial Steering Committee. Glen reviewed and approved the final manuscript, and is a coauthor.

Equality, diversity and inclusion

The trial inclusion/exclusion criteria had no limitations based on gender, LGBTQ preference, ethnicity, social status or geographical location. Children were excluded but are usually managed in different ICUs from adults, experience a different spectrum of illness and are typically studied in paediatric-centric ICU trials.

Blinding

Clinical staff were not blinded to group allocation, as they were managing sedation and titrating the allocated sedatives. Relatives were not formally blinded as part of the trial. We did not record whether relatives had asked or been told which group the patient was allocated to.

Trial registration

This trial is registered as ClinicalTrials.gov NCT03653832.

Analysis

Analysis population

The analysis population comprised all randomised patients in whom nursing and/or relative responses were recorded at least once during the intervention period (and who were not excluded for another reason from the pre-defined overall trial analysis population).⁹ We described the numbers of patients in whom data were available and the mean [standard deviation (SD)] number of days on which responses were available from nurses and from relatives.

Statistical analyses

Baseline characteristics for patients included in the trial have been published previously.⁹ For the present analysis, we summarised relevant baseline data for those patients included in the analysis of nursing responses and visiting relative responses. We calculated the mean (SD) numbers of days with available data for each question, and mean

(SD) proportion of care periods with 'yes' responses to the questions.

We analysed outcomes by fitting a generalised linear mixed model with a logit link function, using all available data. Site was included as a random effect in the model and treatment group as a fixed effect. For these outcomes, which were measured in multiple care periods, a random effect for participant (nested within site) was also included. Results were expressed as the odds ratio (OR) for each of dexmedetomidine and clonidine versus propofol-based sedation, with corresponding 95% confidence interval (CI). A higher OR indicated a greater probability of a 'yes' response to the question analysed.

We recognised that these assessments were most relevant when the patient was either not comatose due to their illness, or concurrent sedation level during the nursing shift was at RASS -3 or higher, indicating patients who were not comatose. In sensitivity analysis, we, therefore, summarised data when the highest RASS score during the concurrent nursing shift was -3 or higher, and repeated the same generalised linear mixed-model analysis restricted to responses for nursing shifts in which a RASS score of -3 or above was recorded.

All analyses were undertaken using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

From December 2018 to October 2023, we randomised 1438 patients in 41 ICUs in the UK. One patient was randomised twice in error. The predefined overall trial analysis population comprised 1404 patients allocated to

receive propofol (N = 471), dexmedetomidine (N = 457) or clonidine (N = 476) as primary sedative. The numbers of patients and proportions of the overall analysis population in whom data were available for this analysis are summarised in [Table 1](#).

A summary of baseline characteristics for the populations analysed is shown in [Table 2](#). Patients included in both the bedside nurse assessments and visiting relative assessments were similar to the published overall trial population. There were no clinically relevant differences between the three groups, or between the subgroup for whom visiting relative assessments were available compared with bedside nursing assessments.

Bedside nurse response to questions

A summary of the bedside nurse responses to the questions is shown in [Table 3](#).

'Is the patient able to communicate pain?' The mean proportion of days with 'yes' response was: dexmedetomidine 39%, clonidine 35% and propofol 33%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 1.38 (95% CI 1.08 to 1.75); for the clonidine with propofol group comparison, the OR for a 'yes' response was 1.13 (95% CI 0.89 to 1.43). Restricting the analysis to days with RASS -3 or above, the mean proportion of days was: dexmedetomidine 44%, clonidine 40% and propofol 37%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was: 1.37 (95% CI 1.07 to 1.74); for the clonidine with propofol group comparison, the OR for a 'yes' response was 1.09 (95% CI 0.86 to 1.38).

'Is the patient able to co-operate with care?' The mean proportion of days was: dexmedetomidine 42%,

TABLE 1 Proportion of patients in the overall trial analysis population contributing data to each of the bedside nurse and visiting relative questions

Question	Proportion of analysis population (number)		
	Propofol	Dexmedetomidine	Clonidine
Bedside nurse			
Is the patient able to communicate pain?	97% (457)	94% (430)	95% (452)
Is the patient able to co-operate with care	93% (438)	90% (413)	92% (438)
Visiting relative			
Does the patient appear awake to the visitor?	34% (162)	32% (148)	34% (164)
Does the patient appear comfortable to the visitor?	33% (156)	32% (147)	34% (160)
Does the visitor feel they can communicate with the patient?	33% (157)	33% (150)	33% (158)

TABLE 2 Comparison of patients' baseline characteristics for the patients in whom: bedside nurse assessments of patients' comfort and communication were recorded, and visiting relative assessments of comfort and ability to communicate were recorded

Variable	Bedside nurse assessments			
	Dexmedetomidine group (N = 456)	Clonidine group (N = 476)	Propofol (N = 471)	Overall cohort (N = 1403)
Mean age (SD)	59 (15)	60 (15)	60 (15)	60 (15)
Male number (%)	283 (66)	297 (66)	295 (65)	875 (65)
Admission APACHE II score mean (SD)	20 (8)	20 (8)	21 (9)	20 (8)
Admission FCI mean (SD)	1.6 (1.5)	1.7 (1.4)	1.6 (1.5)	1.6 (1.4)
Sepsis at baseline number (%)	282 (66)	296 (66)	300 (66)	878 (66)
Diagnostic category number (%)				
Medical	268 (62)	270 (60)	285 (62)	823 (62)
Surgical	130 (30)	140 (31)	141 (31)	411 (31)
Unavailable	32 (7)	42 (9)	31 (7)	105 (8)
Variable	Visiting relative assessments			
	Dexmedetomidine group (N = 153)	Clonidine group (N = 168)	Propofol (N = 164)	Overall cohort (N = 485)
Mean age (SD)	60 (14)	61 (14)	60 (15)	60 (15)
Male number (%)	95 (62)	100 (60)	108 (66)	303 (63)
Admission APACHE II score mean (SD)	20 (9)	20 (7)	21 (8)	20 (8)
Admission FCI mean (SD)	1.7 (1.5)	1.9 (1.4)	1.6 (1.5)	1.7 (1.5)
Sepsis at baseline number (%)	104 (68)	111 (66)	114 (70)	329 (68)
Diagnostic category number (%)				
Medical	103 (67)	105 (63)	110 (67)	318 (66)
Surgical	41 (27)	52 (31)	43 (26)	136 (28)
Unavailable	9 (6)	11 (7)	11 (7)	31 (6)

APACHE II, Acute Physiology and Chronic Health Evaluation; FCI, Functional Comorbidity Index.

clonidine 38% and propofol 38%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 1.14 (95% CI 0.98 to 1.32); for the clonidine with propofol group comparison, the OR for a 'yes' response was 0.96 (95% CI 0.83 to 1.12). Restricting the analysis to days with RASS –3 or above, the mean proportion of days was: dexmedetomidine 46%, clonidine 42% and propofol 42%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 1.11 (95% CI 0.95 to 1.30); for the clonidine with propofol group comparison, the OR for a 'yes' response was 0.94 (95% CI 0.80 to 1.09).

Visiting relative responses to questions

A summary of the visiting relative responses to the questions is shown in [Table 4](#).

'Does the patient appear awake to the visitor?' The mean proportion of days was: dexmedetomidine 53%, clonidine 50% and propofol 44%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 1.48 (95% CI 1.04 to 2.10); for the clonidine with propofol group comparison, the OR for a 'yes' response was 1.35 (95% CI 0.95 to 1.91). Restricting the analysis to days with RASS –3 or above, the mean proportion of days was: dexmedetomidine 56%, clonidine 54% and propofol 49%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 1.31 (95% CI 0.93 to 1.85); for the clonidine with propofol group comparison, the OR for a 'yes' response was 1.25 (95% CI 0.89 to 1.77).

'Does the patient appear comfortable to the visitor?' The mean proportion of days was: dexmedetomidine

TABLE 3 Bedside nurses' assessments of ability to communicate pain and co-operate with care

Outcome	All available care periods included				Care periods restricted to RASS score –3 or greater			
	Dexmedetomidine (N = 430)	Clonidine (N = 452)	Propofol (N = 457)	Overall (N = 1339)	Dexmedetomidine (N = 418)	Clonidine (N = 434)	Propofol (N = 439)	Overall (N = 1291)
Ability to communicate pain								
Number of care periods for which patient was able to communicate pain – number (percentage)	319 (74)	315 (70)	313 (69)	947 (71)	316 (76)	313 (72)	309 (70)	938 (73)
Number of care periods per patient during follow-up, for which communication of pain data were available – mean (SD)	12 (12)	12 (11)	12 (12)	12 (12)	10 (10)	11 (11)	11 (11)	10 (11)
Number of care periods per patient during follow-up, for which patient able to communicate pain – mean (SD)	5 (8)	4 (7)	4 (8)	5 (7)	5 (8)	4 (7)	5 (8)	5 (7)
Percentage of care periods per patient during follow-up, for which patient was able to communicate pain – mean (SD)	39% (35)	35% (33)	33% (33)	36% (34)	44% (36)	40% (35)	37% (35)	40% (35)
Ability to co-operate with care	Dexmedetomidine (N = 413)	Clonidine (N = 438)	Propofol (N = 438)	Overall (N = 1289)	Dexmedetomidine (N = 401)	Clonidine (N = 419)	Propofol (N = 420)	Overall (N = 1240)
Number of care periods for which patient was able to co-operate with care – number (percentage)	329 (80)	325 (74)	329 (75)	983 (76)	319 (80)	319 (76)	319 (76)	957 (77)
Number of care periods per patient during follow-up, for which co-operation with care data were available – mean (SD)	11 (10)	11 (11)	11 (11)	11 (10)	9 (9)	10 (10)	9 (10)	9 (10)
Number of care periods per patient during follow-up, for which patient was able to co-operate with care – mean (SD)	5 (7)	4 (7)	5 (7)	5 (7)	5 (6)	4 (7)	5 (7)	5 (7)
Percentage of care periods per patient during follow-up, for which patient was able to co-operate with care – mean (SD)	42% (33)	38% (33)	38% (33)	39% (33)	46% (35)	42% (34)	42% (34)	43% (34)

TABLE 4 Visiting relative assessments of whether patient appears awake or seems comfortable and whether they feel able to communicate with patient

Outcome	All available days included				Days restricted to RASS score –3 or greater			
	Dexmedetomidine (N = 148)	Clonidine (N = 164)	Propofol (N = 162)	Overall (N = 474)	Dexmedetomidine (N = 144)	Clonidine (N = 158)	Propofol (N = 151)	Overall (N = 453)
Patient appears awake to the visiting relative								
Number of days recorded on which patient appeared awake to the visitor – number (percentage)	109 (74)	108 (66)	100 (62)	317 (67)	107 (74)	108 (68)	99 (66)	314 (69)
Number of days during follow-up, for which data available regarding whether patient appears awake to the visiting relative – mean (SD)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)
Number of days during follow-up on which patient appears awake to the visiting relative – mean (SD)	2 (2)	2 (2)	1 (2)	2 (2)	2 (2)	2 (2)	2 (2)	2 (2)
Percentage of days during follow-up, for which patient appears awake to the visiting relative – mean (SD)	53% (40)	50% (42)	44% (41)	49% (41)	56% (40)	54% (42)	49% (41)	53% (41)
Patient seems comfortable to the visitor								
Number of days recorded on which patient appeared comfortable to the visitor – number (percentage)	140 (95)	153 (96)	152 (97)	445 (96)	137 (96)	148 (96)	141 (97)	426 (96)
Number of days during follow-up, for which data available regarding whether patient appears comfortable to the visiting relative – mean (SD)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)	3 (3)
Number of days during follow-up on which patient appeared comfortable to the visitor – mean (SD)	3 (2)	3 (3)	3 (3)	3 (3)	3 (2)	2 (3)	3 (3)	3 (3)
Percentage of days during follow-up on which patient appeared comfortable to the visitor – mean (SD)	88% (26)	90% (24)	93% (19)	90% (23)	89% (25)	91% (23)	93% (20)	91% (23)
Visiting relative feels they can communicate with the patient								
Number of days for which the visitor feels they can communicate with the patient – number (percentage)	107 (71)	102 (65)	104 (66)	313 (67)	107 (73)	100 (66)	102 (69)	309 (70)
Number of days during follow-up, for which data available regarding whether relative feels able to communicate with patient – mean (SD)	3 (3)	3 (3)	3 (3)	3 (3)	3 (2)	3 (3)	3 (3)	3 (3)
Number of days during follow-up for which the visitor feels they can communicate with the patient – mean (SD)	2 (2)	2 (2)	2 (3)	2 (2)	2 (2)	2 (2)	2 (3)	2 (2)
Percentage of days during follow-up, for which the visitor feels they can communicate with the patient – mean (SD)	54% (41)	52% (44)	52% (42)	52% (42)	56% (41)	54% (44)	57% (43)	56% (42)

88%, clonidine 90% and propofol 93%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 0.64 (95% CI 0.38 to 1.09); for the clonidine with propofol group comparison, the OR for a 'yes' response was 0.78 (95% CI 0.45 to 1.34). Restricting the analysis to days with RASS ≥ -3 or above, the mean proportion of days was: dexmedetomidine 89%, clonidine 91% and propofol 93%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 0.58 (95% CI 0.33 to 1.02); for the clonidine with propofol group comparison, the OR for a 'yes' response was 0.70 (95% CI 0.39 to 1.25).

'Does the visitor feel they can communicate with the patient?'

The mean proportion of days was: dexmedetomidine 54%, clonidine 52% and propofol 52%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 1.00 (95% CI 0.68 to 1.47); for the clonidine with propofol group comparison, the OR for a 'yes' response was 1.05 (95% CI 0.71 to 1.54). Restricting the analysis to days with RASS ≥ -3 or above, the mean proportion of days was: dexmedetomidine 56%, clonidine 54% and propofol 57%. Comparing the dexmedetomidine with propofol group, the OR for a 'yes' response was 0.87 (95% CI 0.59 to 1.30); for the clonidine with propofol group comparison, the OR for a 'yes' response was 0.96 (95% CI 0.64 to 1.42).

Discussion

In this preplanned analysis of the A2B trial,⁹ we found that, overall, bedside nurses felt patients were able to communicate pain in a mean 36% of care periods. Comparing each alpha2-agonist to propofol-based sedation, dexmedetomidine was associated with greater probability of being able to communicate pain; the probability for clonidine was similar to propofol-based sedation. Overall, bedside nurses felt patients were able to co-operate with care for a mean 39% of care periods, with no significant differences between either dexmedetomidine or clonidine and propofol. Overall, visiting relatives felt patients appeared awake for a mean of 49% of days they visited. Comparison of dexmedetomidine and clonidine to propofol-based sedation suggested effects that favoured both alpha2-agonists compared with propofol, but the CI only excluded a null effect for the dexmedetomidine to propofol comparison. Relatives felt patients appeared comfortable for a mean of 90% of days they visited. There were no marked differences between groups, but the observed effects and CIs indicated a trend towards greater perceived comfort with propofol. Finally, relatives felt they could communicate with patients on a mean of 52% of

days they visited, with no apparent differences between the groups.

To our knowledge, this is the first exploration of nurses' and relatives' perceptions of patient comfort and ability to communicate during ICU sedation. Embedding this substudy within a randomised trial enabled direct comparison between sedation with the three strategies. The proportion of trial patients (> 90%) and numbers of care periods with data (mean 11–12 care periods, equating to 6 days) was high for the bedside nurse responses. Given the study occurred in 41 ICUs over 5 years, with data recorded by nurses providing clinical care, it is likely that several thousand different nurses contributed opinions. The study, therefore, has high validity for representing nurse opinions, based on the questions asked. Approximately, a third of patients had opinions from visiting relatives, and for a smaller number of days per patient (mean 3 days). The smaller sample resulted from several factors. First, the ethics committee approval only allowed the relative who had provided consent for each participant in the trial to provide views, which restricted data to days on which they visited. Second, the COVID-19 pandemic had an extended effect on relative visiting behaviours during much of the trial. Despite this, we obtained views from 474 different relatives distributed evenly across the three groups. The patients in whom relative responses were available had similar baseline characteristics to the overall trial cohort, suggesting inclusion bias was unlikely.

Guidelines recommend the clinical assessment of sedation state, pain status and cognition using validated scales designed to have high discriminative ability and inter-rater consistency.⁷ As such, they do not reflect nurses' personal views and nurse preferences. These can be discordant with guidelines, for example, in relation to performing sedation breaks and/or maintaining wakefulness, and because of concerns about patient comfort, distress and safety.^{11–13} Factors such as personal beliefs and previous experiences, for example, adverse events, are also potentially important,^{11–14} and practices such as increasing overnight sedation to promote sleep and safety are common.¹⁵ Our approach sought nurse and relative views based on their personal opinion, providing novel insights into sedation quality from these perspectives. This is relevant to understanding sedation practice and clinician preferences, given the complex interplay of factors involved in sedation delivery.^{11,14}

Dexmedetomidine aims to achieve light sedation where patients are readily roused, more co-operative, and interactive when stimulated.⁷ This may be mediated by clearer cognition and reduced delirium.^{16–18} Analgesic

properties also potentially contribute to patient comfort. These benefits underpinned our hypothesis that nurse and relative views would demonstrate superiority compared with propofol. In the A2B trial, patients first achieved the target RASS of -2 after a median 24 hours in all three groups, and on around 75% of intervention days, demonstrating that attempts were made to maintain light sedation.⁹ This was also reflected in the high proportion of care periods available for analyses restricted to RASS score -3 or greater. Our findings are consistent with the proposed benefits of dexmedetomidine in relation to nurse communication and relative perceptions of wakefulness, although CIs were wide. The lesser effect with clonidine is consistent with its much lower alpha2-receptor selectivity. In the trial, we found no differences between the groups in rates of unnecessary deep sedation, delirium or pain behaviours, but agitation occurred at a 50% higher rate in both alpha2-agonist groups compared with propofol.⁹ This might explain why nurses reported no significant differences in the ability to co-operate with care, and relatives reported no significant differences in perceived ability to communicate. Relative assessment of comfort may have had a ceiling effect, as mean proportions were 88–93% across the groups. The trend to greater perception of comfort with propofol compared to both alpha2-agonists was unexpected, but might be explained by the greater agitation rates with alpha2-agonists. For all questions, the CIs from the modelling included a wide range of potentially important differences between the groups, perhaps reflecting the sample size available for analysis, diversity of views from nurses and relatives, and differences between individual patients.

Strengths of this substudy include the randomised design, large sample size especially for the nurse data, and pragmatic real-world context. Patients were also closely involved throughout the design, data collection, analysis and interpretation of the data. Our analytic approach included modelling that maximised use of available data with adjustment for site and multiple observations within participants. However, our study has limitations. Data were not available every day, with only a third of patients contributing relative data. The populations with data were similar to the overall trial, but we cannot exclude some inclusion or response bias. Group allocation was not blinded, which might have influenced subjective responses, especially among bedside nurses. Although sedation was randomised, most patients in the alpha2-agonist groups also received some propofol, at around a third of UC dose, which meant the responses did not reflect sedation with alpha2-agonists alone in most cases. The majority of patients also received opioid infusions at the discretion of clinical teams.

Future research should further investigate the differences in perceived sedation quality from carer and relative perspective with different drugs and sedation strategies, potentially using opinion-based tools as in this study and/or qualitative methods. To investigate whether differences translate into improvements in clinical or patient-centred outcomes, the relationship between improved communication or wakefulness and changes in care decisions (e.g. earlier weaning or mobilisation) or family satisfaction could be explored.

In conclusion, although the A2B trial found no significant differences in objective measures of sedation status (RASS score), delirium (CAM-ICU scores) or pain behaviours, this substudy suggested that nurses may perceive patients receiving dexmedetomidine as better able to communicate pain compared with propofol. There did not appear to be perceived differences in ability to co-operate with care for either alpha2-agonist versus propofol. Visiting relatives perceived patients appeared more awake with dexmedetomidine compared with propofol. Perceptions of comfort and ability to communicate were not notably different between groups, although CIs did not rule out large effect sizes. Given the primary and other key clinical outcomes in the A2B trial were not superior with dexmedetomidine or clonidine compared to propofol, the implications of these findings for optimising ICU sedation are uncertain and reflect the complexity of ICU sedation practice.

Additional information

CRedit contribution statement

Timothy S Walsh (<https://orcid.org/0000-0002-3590-8540>): Conceptualisation (lead), Formal analysis (supporting), Funding acquisition (lead), Investigation (equal), Methodology (equal), Administration (equal), Supervision (lead), Visualisation (equal), Writing – original draft (lead), Writing – reviewing and editing (equal).

Richard A Parker (<https://orcid.org/0000-0002-2658-5022>): Data curation (equal), Formal analysis (lead), Investigation (supporting), Methodology (equal), Software (lead), Validation (lead), Visualisation (equal), Writing – reviewing and editing (equal).

Leanne M Aitken (<https://orcid.org/0000-0001-5722-9090>): Conceptualisation (supporting), Funding acquisition (supporting), Investigation (supporting), Methodology (supporting), Administration (supporting), Supervision (supporting), Visualisation (equal), Writing – reviewing and editing (equal).

Cathrine A McKenzie (<https://orcid.org/0000-0002-5190-9711>): Conceptualisation (supporting), Funding acquisition (supporting), Investigation (supporting), Supervision (supporting), Visualisation (equal), Writing – reviewing and editing (equal).

Robert Glen (<https://orcid.org/0009-0007-6001-8578>): Conceptualisation (supporting), Funding acquisition (supporting), Investigation (supporting), Visualisation (equal), Writing – reviewing and editing (equal).

Christopher J Weir (<https://orcid.org/0000-0002-6494-4903>): Conceptualisation (supporting), Data curation (supporting), Formal analysis (lead), Funding acquisition (supporting), Investigation (supporting), Methodology (lead), Administration (supporting), Software (supporting), Supervision (supporting), Validation (lead), Writing – reviewing and editing (equal).

Acknowledgements

The A2B trial investigators, who all contributed to the data presented in this analysis, are listed in [Appendix 1](#).

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: <https://understandingpatientdata.org.uk/data-citation>

Data-sharing statement

De-identified participant data will be made available to researchers if their proposal for use is within the agreed uses for which participants provided consent, the proposal is approved by the trial team, and any agreements are in place for data-sharing. A data dictionary for the trial data will be made available. All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

The A2B trial received ethical approval from the Scotland A REC (18/SS/0085) on 21 August 2018.

Information governance statement

The University of Edinburgh and NHS Lothian (cosponsors) are committed to handling all personal information in line with the

UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Edinburgh is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer, here (<https://data-protection.ed.ac.uk/contact>). The University of Edinburgh is also the Data Processor.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at <https://doi.org/10.3310/GJTW2718>.

Primary conflicts of interest: Timothy S Walsh declares receiving a grant from NIHR EME Board as a co-applicant and a grant from NIHR Programme Board as a co-applicant. Neither grant related to this work, and funding was to the University of Edinburgh.

Richard A Parker declares membership of the HS&DR Board (31 July 2013–31 May 2018).

Cathrine A McKenzie declares being in receipt of an NIHR Senior Clinical Practitioner Research Award, and an NIHR Wessex Applied Research Collaborative Research Enhancement Award.

Christopher J Weir declares membership of several boards: HS&DR Commissioned – Board Member (31 July 2013–1 March 2016); HS&DR Commissioned R&R (Bird) Sub Board (31 July 2013–1 May 2016); HS&DR Funding Committee Member (31 July 2013–31 January 2018); and EME – Funding Committee Member (1 July 2018–1 July 2022).

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This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Trial registration

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List of abbreviations

A2B	Alpha 2 agonists for sedation to produce Better outcomes from critical illness
CAM-ICU	Confusion Assessment Method for the ICU

ICU	intensive care unit
LGBTQ	lesbian, gay, bisexual, transgender and queer
MV	mechanical ventilation
PerLegR	Personal Legal Representative
PPI	patient and public involvement
RASS	Richmond Agitation–Sedation Scale
REC	Research Ethics Committee
UC	usual care

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Appendix 1 Members of the A2B Trial Investigators Group

Natalie Pattison
Barry Williams
Louise Rose
Paul Mouncey
John Prowle
David Wellsted
Stephen Brett
Julian Bion
Graeme McLennan
Matt Stevenson
Alistair Nichol

Timothy Walsh
Maria Amamio
Lucy Barclay
Sophie Birch
Kate Briton
Sarah Clark
Jessica Crossan
Katherine Doverman
David Hope
Lucy Macdonald
Corrienne McCulloch
Nicola Rae
Scott Simpson
Jo Singleton
Maggie Wishart

Ruth Thompson
 Neill Aitken
 Rachel Fairlie
 Nabeel Salim
 Sam Talbot
 Sarah Ackroyd
 Valeria Alicino
 Euan Allan
 Thomas Anderson
 Rosemary Andrew
 Andrew Baigey
 Kenneth Baillie
 Calum Barnettson
 Ruth Begbie
 Richie Biggers
 Michael Blaney
 Richard Broom
 David Birrell
 Will Calkin
 Keegan Chuavilong
 Rebecca Cowden
 Thomas Cox
 Coral Darjee
 Simon Davies
 Annemarie Docherty
 Luke Dornan
 Mark Dunn
 Stuart Edwardson
 Ross Gillespie
 Jane Greenwood
 David Griffith
 Alasdair Hay
 Amy Hu
 Ali Hunter
 Karen Jones
 Helen Jordan
 Ancy Joseph
 Kallirroi Kefala
 Stephanie Kelly
 Laura Kemp
 Bara Kubanova
 Victoria Leng
 John Livesey
 Nazir Lone
 James Lyon
 Olivia Mansfield
 Dean McAvoy
 Aaron McClatchey
 Jonathan Miller
 Ananda Mirchandani
 Peter Moffitt
 Steven Morrison
 Alexandra Muir

Kieran Nunn
 John Ochiltree
 Emily Ogden
 Matthew Parks
 Marc Pass
 Rachael Penrose
 Harry Putnam
 Thomas Quinn
 Jonathan Rhodes
 Alexander Rollings
 Stephen Ross
 Ralph Shackleton
 Manu Shankar
 Sunil Sharma
 Iain Slessor
 Zack Slevin
 Duncan Stickle
 Louise Symons
 Fiona Walker
 Luke Walls
 Ian Whiteford
 Sue Yin Yong
 Neil Young
 Kevin Rooney
 Michael Kinsella
 Brian Digby
 Michael Brett
 Paul McConnell
 Mark Henderson
 Radha Sundaram
 Lisa Gemmell
 Fiona Christie
 Philip Henderson
 Fiona MacGregor
 Steven Henderson
 Natalie Rodden
 Kirsty Fallon
 Lynn Abel
 Barbara McLaren
 Emma Hughes
 Deborah McGlynn
 Nicola Thomson
 Lauren Walker
 Susan Currie
 Natasha Parker
 Donna Gillan
 Farooq Brohi
 Sarah Purvis
 Michele Clark
 Pam Race
 Lynne Williams
 Ahmed Shahin
 Eusebius Nworah

Jonathan Gui
Li-Chin Cheng
Katelyn Stewart
Rebecca Cusack
Mark Tomlin
Clare Bolger
Rachel Burnish
Sue Jackson
Alice Baker
Jonathan Biss
Karen Salmon
Michael Carter
Catherine McKenzie
Razaz Elsheikh
Missy (Anne) Harrison
Charlotte Thomas
James Ward
Andrew Cumpstey
Ahilanandan Dushianthan
Ivan Kemp
Valerie Page
Xiaobei Zhao
Nazril Nordin
Ahmed Hegazy
Elvira Hoxha
Owen Hardaker
Chimenime Ede
Nailia Kotrikova
Acharya Devaraja
Thomas Stambach
Prasun Mukherjee
Mark Louie Guanco
Matthew P Wise
Jade Cole
Helen Hill
Jenny Brooks
Michelle Davies
Rhys Davies
Emma Thomas
Angharad Williams
Lauren Lodhi
Matt PG Morgan
Simon Ridler
Christopher Smith
Maria Faulkner
Alison Ivison
Laura McKay
Helen Jeffrey
Jude Price
Lucy Slater
Angela Davies
Edward Hughes.
Matt Thomas

Dominic Janssen
Ian Thomas
Kate Crewdson
Christopher Newell
Robert Hirst
Stephen West
Agnieszka Skorko
Emma Gendall
Ruth Worner
Beverley Faulkner
Borislava Borislavova
Kati Hayes
Andrew Parsons
Elizabeth Goff
John Sowersby
Annie Wood
Kieran Oglesby
Idrisu Sanusi
Charlie Pope
Andrew Baird
Hayley Blackmore
Robert Healey
Philip Hopkins
Eleanor Corcoran
Gillian Selman
Clare Finney
Evita Pappa
John Smith
Emma Clarey
Maeve Cockrell
Sian Saha
Harriet Noble
Kevin O'Reilly
Maria Depante
Anna Broderick
Marianette Anne
Axalan Burt
Vergara Reena Mehta
Henrik Reschrieter
Sarah Patch
Julie Camsooksai
Sarah Jenkins
Madga Pomichowska
Ken Power
Spike Briggs
Elizabeth Woodward
Christopher Loew
James Bromilow
James Keegan
Matthew Taylor
Emma Langridge
Dinesh Kulandhaisamy
Saah Savage

Yasmin de'Ath
 Charlotte Humphrey
 Sue Roffe
 Matthew Bayliss
 Leanne Bartlett
 Richard Gordon-Williams
 Kate Tatham
 Sam Smith
 Isabel Noris
 Sharjeel Tahir E
 mma Yates S
 hivali Patel
 Tanith Westerman
 Sekina Bakare
 Hugh Furness
 Emma Hunt
 Reyhaneh Sadegh Zadeh
 Maria Khan
 William Sherwood
 Claudio Addari
 Roshni Manex
 Nicole Whitehead
 Fred Wilson
 Luke Edwards
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 Sophie Biddle
 Suzannah Lant
 Francesca Holden
 Shree Voralia
 Nicola Ocean
 Arun Sahni
 Prakhar Srilastava
 Sultan Iqbal
 Shamil Tana
 Vishal Venkat Raman
 Zoszka Webb
 Luke Parker
 Arnold Dela Rosa
 Miran Kadr
 Eleanor Harvey
 Ryan Howle
 Aatif Husain
 Olivia Morley
 Sarah Loftus
 Jenna Hutchinson
 Shaman Jhanji
 Ethel Black
 David Parkinson
 Ravishankar Raobaikady
 Mark Borthwick
 Christie James
 Grace Polley
 Neil Davidson

Sally Beer
 Paula Hutton
 Archana Bashyal
 Jean Wilson
 Soyamol Mathew
 Jung Ryu
 Jason Cupitt
 Gareth Hardy
 Leonie Benham
 Robert Downes
 Neil Flint
 Michael Little
 Ravindra Pochiraju
 Prematie Andreou
 Dawn Hales
 Jessica Hailstone
 Megha Mathews
 Martin Huntley
 Lorraine Stephenson
 Jacqui Hussey
 Hao-Ern Tan
 Simon Holbrook
 Hayley Kemp David Earl
 Richard Innes
 Benjamin Plumb
 Patricia Doble
 Rebecca Purnell
 Ashly Thomas
 Muhammad Hamza Noor
 Waqas Khaliq
 Micheal Jennings
 Bernd Oliver Rose
 Rosaleeta Reece-Anthony
 Sagira Khatun
 Samantha Dickinson
 Jayson Clarke
 Charlie Cox
 Adam Longley
 Tariq Ali
 Babita Gurung
 Mohamed Moubarak
 Alan Williams
 Jonathan Ball
 Susannah Leaver
 Sarah Farnell-Ward
 Maria Thanasi
 Shreeja Dangol
 Vince Ventura
 Massimiliano Valcher
 Christine Sicat
 Nikki Yun
 Rebecca Kanu
 Maria Maiz Cordoba

Ha Trinh
Karen Lloyd
Romina Pepermans Saluzzio
Lijun Ding
Helen Farrah
Edna Fernandes
Chris Nutt
Jon Silversides
Danny McAuley
Peter McGuigan
Emmet Major
Elliott Lonsdale
Nerielle Fundano
Kathryn Ward
Christine Turley
Aisling O'Neill
Stephanie Finn
Jackie Green
Erin Collins
Julie McAuley
Jeanette Mills
Chris Wright
Michelle Growcott
Iain McCullagh
Stephen Wright
Ian Clement
Jonathan Shelton
Matthew Faulds
Thomas Hellyer
Harriet Morton
Christopher Pollard
Christopher White
Leigh Dunn
Verity Calder
Susan Taylor
Pamela Garcia
Benjamin Brown
James Savage
Maite Babio-Galan
Kimberley Webster
Tessa Wilkinson
Arti Gulati
Tara Shrestha
Carole Hays
Lauren Butler
Fatima Simoes
Margaret McNeil
Ian Storey
Simon Whiteley
Elizabeth Wilby
Susan Trott
Sarah Watts
Shailamma Mathew

Sheila Salada
Adam Neep
Nora Youngs
Clare Howcroft
Matthew Powell
Michael Adlam
Elankumaran Paramasivam
Zoe Friar
David Antcliffe
Stephen Brett
Anthony Gordon
Dorota Banach
Roceld Rojo
Sonia Sousa Arias
Ziortza Fernandez de Pinedo Artaraz
Phoebe Coghlan
Amal Mohammed
Eleanor Jepson
Jenny Wong
Anita Tamang Gurung
Caoimhe O'Dwyer
Sara Perez Guillotin
Maie Templeton
James Hanison
Jonathan Bannard-Smith
Daniel Conway
Shoneen Abbas
Mohamad Aly
Stephen Benington
Teh Eng Hean
Daniel Hayley
Ellen McGuckin
Andrew Martin
Thomas Morris
William Musselbrook
Bhaskar Narayan
Thomas Wright
Chris Wheeler
Melanie Barker
Richard Clark
Emma Connaughton
Rose Jama
Deborah Paripoorani
Rachael Quayle
Anila Sukumaran
Charlotte Taylor
Megan Balmer
Saejohn Lingeswaran
Lauren Edmunds
Katharine Wylie
Andrew Owen
Gavin Perkins
Sean Munnelly

Daniel Park
 Jo Gresty
 Ellie Reeves
 Celina Maliaykal
 Teresa Melody
 Jacobus Preller
 Petra Polgarova
 Cristina Bravoelvira
 Sofia Teixeira
 James Varley
 Sapna Sharma Hajela
 Kay Elston
 Siobhan Campbell
 Meike Keil
 Muhammad Elbehery
 Jocelyn Marshall
 Susan Stevenson
 Andrew Conway Morris
 Prasad Gogineni Venkateskara
 Michael Reay
 Karen Reid
 Rebecca Brown
 Chinenyenwa Amareihe
 Elliot Yates
 Jia Luen Goh
 Edward Jones
 Aamer Mughal
 David Brealey
 Niall MacCallum
 Samuel Clark
 Deborah Smyth
 Georgia Bercades
 Ingrid Hass
 Gladys Martir
 Jung Ryu
 Anna Reyes
 Maria Alexandra Zapata Martinez
 Laura Gallagher
 Chi Yee Chung
 Graeme Sanders
 Vipal Chawla
 Namrata Maheshwari
 Tessa Glazebrook
 Hollie Angel
 Rebecca Squires
 Hayley Dolan
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 Tanushree Santra
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 Andrew Russell
 Viresh Patel
 Upasana Topiwala
 Habideen Bello
 Julia Sampson
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 Louise Conner (Now Hughes)
 Lucy Morris
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 Alice Baddeley
 Lisa Mcloughlin

Cate Walton
Treesa Joseph
Anju Thomas
Sophie Lubbock
David Ford
Alexandra McCoy
Tony N'Dungu
Ingeborg Welters
Vinoth Sankar
Alicia Waite
Brian Johnston
David Shaw
Vicki Waugh
Karen Williams
Maria Lopez Martinez
Maria Norris
Maria Arra Carlota Mahiya
Jamie Fernandez Roman
Jin-Xi. Yuan
Silvia Manes
Caitlin Lythgoe
Ibrahim Almafretti
Josh Colfar
Laura Medhurst
Stephanie Beresford
Sofia Farina
Lema Imam
Syamlam Ali Zachary
Thomas Francesca Bold
Edward Hughes
Katherine Hodson A
leem Morenikeji
Daniel Watkin
Tamas Szakmany
Amy Cardwell
Anne Frawley
Marlies Ostermann
Gillian Radcliffe
Nicholas Barrett
Simon Sparkes
Adam Woodman-Bailey
Eirini Kosifidou
Aneta Bociek

Ellie Hendrie R
osario Lim
Fabiola D'Amato
Sarah Fordyce
Benjie Cendreda
Kyma Morera Vas
Jacqueline Pan
Christopher Meddings
Vladimir Milic
Mike Barker
Jennifer Owusu-Afriyie
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Izabela Orlikowska
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Samantha Hagan
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Alasdair Hay
Jian Que
Stephen Wilson
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Emma Collins
Miqdad Ibrahim
Mark Wheeley
Mostafa Kodous
Mathew Blake
Victoria Lacey
Michael Eager
Robin Jootun
Janine Birch