Risk of complications using a sedation protocol for aeromedical retrieval of acutely unwell mental health patients: a retrospective cohort study in Outback Australia

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ABSTRACT

Background Aeromedical transfer of acutely unwell mental health (AMH) patients presents potential risks to patient, staff and aircraft. Pharmacological options to reduce risk can impair consciousness, risking airway compromise and management challenges in-flight. Pre-emptive intubation carries associated patient risks and requires a receiving intensive care unit bed. This study aimed to assess the risk of complications using a protocolised approach to sedation of AMH patients undergoing retrieval in New South Wales, Australia.

Methods This retrospective cohort study included all aeromedical transfers of AMH patients performed by the Royal Flying Doctor Service South Eastern Section (RFDSSE) between 1 January 2011 and 31 December 2022. AMH patients whose treatment during transfer aligned with the RFDSSE Mental Health (MH) transfer protocol ('On Protocol', OnP) were compared against the 'Off Protocol' (OffP) group. Patient characteristics (MH risk assessment score), transfer characteristics (duration), medications administered and complications (any, severe) experienced were compared using univariate analyses.

Results Treatment aligned with MH transfer protocol (ie, OnP) in 45.9% (n=39) of 85 cases. Complications were more common in the OffP group (54.3% vs 25.6%, a difference of 28.7% (95% CI 7.8% to 46.2%)). Similarly severe complications occurred more frequently in the OffP group (37.0% vs 5.1%, a difference of 31.8% (95% CI 14.7% to 46.7%)). Intubated patients (n=9, all OffP) had the highest rate of severe complications at 66.7%, followed by patients who received midazolam (n=33, all OffP), with a severe complication rate of 30.3%.

Conclusion A protocolised approach to sedation of AMH patients undergoing aeromedical retrieval, including the use of ketamine sedation, was associated with fewer complications overall, fewer severe complications and no episodes of treatment failure or need for intubation. Our findings suggest that the use of midazolam and/or intubation in this cohort is associated with a higher risk of complications, and ketamine presents a safer alternative.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Ketamine has a good safety profile for sedation of acute behavioural disturbance in both emergency department and aeromedical transfer settings.
⇒ Protocolised use of ketamine for acutely unwell mental health patients requiring aeromedical transfer has not been studied.

WHAT THIS STUDY ADDS

⇒ Protocolised sedation of acutely unwell mental health patients in the retrieval setting is associated with fewer complications and need for intervention.
⇒ Midazolam use is associated with more severe complications, as is endotracheal intubation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Retrieval services should implement a sedation protocol that includes the use of ketamine and avoids the use of midazolam and intubation.

INTRODUCTION

Australia faces unique challenges providing specialist medical care to a dispersed population. As the sixth largest country in the world with 5% of the world's landmass, Australia has a population of 26 million people, 86% of whom live in urban areas[1] and the remainder in rural and remote areas. This has driven several innovations such as the establishment of the Royal Flying Doctor Service (RFDS). The RFDS South Eastern Section (RFDSSE) delivers medical services to Australians across an area as large as France through aeromedical bases in Dubbo and Broken Hill, providing care to isolated people and communities in rural and remote New South Wales, parts of South Australia and Queensland. The RFDSSE retrieval service recruits doctors from emergency medicine, anaesthetics and intensive care backgrounds. These doctors perform remote telehealth and coordinate retrievals across this area that can be flight nurse only or a doctor-flight nurse retrieval. Retrieval taskings can come as self-taskings from RFDS clinicians, from the Aeromedical Control Centre (ACC) in Sydney or alternative telehealth services. Pre-retrieval telehealth care may therefore differ depending on the service or principal specialty of the tasking clinician.

Rates of mental health conditions are higher for rural Australians,[2] mental health facilities are scarce, and provision of inpatient mental healthcare is focused in only a few centres, making aeromedical transfer a frequent necessity. Never has the tyranny of distance been greater than for an acutely unwell mental health (AMH) patient presenting to a remote medical facility and requiring urgent care. The RFDSSE fills this void, and mental health patients account for 3.3% of aeromedical transfers, equivalent to the number of patients transferred with sepsis (3.0%).

AMH patients frequently present with agitation, a significant challenge to manage in remote locations with limited resources and staff. Small rural clinics are often staffed by a single registered nurse (RN), usually on call after hours. An agitated or psychotic patient who presents to a rural facility may require several hours of high-level care prior to retrieval, placing huge demands on a rural facility with limited staffing.

Management of the AMH patient may involve non-pharmacological methods such as verbal de-escalation, physical restraint and pharmacological sedation. Management of very agitated patients such that they can be safely transferred often requires significant doses of sedatives, and historically, the safest approach has been considered general anaesthesia and endotracheal intubation. This has been challenged by a number of recent studies. A small case series showed ketamine sedation could be used to safely transport AMH patients without intubation.[3] Two studies showed ketamine sedation in aeromedical transfer of patients with acute behavioural disturbance (ABD) was safe[4 5] and reduced intubation rates.[4] To the authors' knowledge, no studies have addressed the use of a structured sedation protocol in this patient group, focussing instead on the use of single agents. Of the previously mentioned recent studies, both have examined patients with undifferentiated ABD, where we sought to apply our protocol to purely mental health patients, through filtering by ICD-10 codes (International Statistical Classification of Diseases and Related Health Problems 10th Revision) and excluding those intoxicated by substance misuse.

Given the heterogeneity of tasking services, personnel involved and pharmacological treatment options in mental health (MH) transfers, RFDSSE introduced a MH transfer protocol in 2015, aligning with the Australian Aeromedical Retrieval Services consensus document from 2015.[6]

The aim of this retrospective cohort study was to determine whether a protocolised sedation approach, including the use of ketamine, is associated with fewer complications and improved safety during aeromedical transfers.

METHODS

RFDSSE MH transfer protocol

RFDSSE practice begins with a mental health risk assessment using a risk assessment tool, stratifying patients into low, medium and high risk which then mandates which crew must be present (flight nurse (FN)±medical officer (MO)) and whether sedation and/or restraint is required (figure 1).

An anaesthetic risk assessment is also undertaken to consider the patient's physiological reserve and risk of airway compromise.

Risk Assessment Tool

Patient's Name:_____D.O.B:_____

Gender: M/F

Subject area	Y/N	Score	Comments
Any known history of violence to persons or property?		10	
Any expression of anger, frustration or agitation during course of hospital admission or preceeding 24 hours?		5	
Multiple expressions of anger, frustration or agitation during current care, requiring special nursing or security measures or chemical restraint/sedation?		20	
Signs of intoxication/withdrawal from drugs or alcohol during course of hospital admission or preceding 24 hours?		10	
Known history of substance abuse (alcohol, opioids, amphetamines, marijuana)?		5	
Known environmental stressors in last 7 days (personal loss, relationship crisis, financial crisis etc)?		5	
TOTAL SCORE			

High risk (>25): FN + MO. Patient sedated and restrained. Consider intubation and ventilation if failed trial of pre-flight sedation. IV access present.

Medium risk (6-24): FN + MO. Patient sedated and restrained. IV access present.

Low risk (0-5): FN +/- MO. May require sedation. Restrained and IV access present.

Figure 1 Mental health risk assessment. FN, flight nurse; IV, intravenous; MO, medical officer.

Recommended drugs and doses for sedation of Mental Health Patients

	No IV access	IV access established
1st line	Olanzapine 10-20mg PO (max 30mg/24hrs) +/- Diazepam 10-20mg PO	Droperidol 5-10mg IV (max 20mg/24hrs)
2nd line	Droperidol 10mg IM	Ketamine 1-1.5mg/kg IV +/- Ketamine 1-1.5mg/kg/hr IV infusion
3rd line	Ketamine 3-5 mg/kg IM	Consider RSI

Figure 2 Royal Flying Doctor Service South Eastern Section sedation protocol. IM, intramuscular; IV, intravenous; RSI, Rapid Sequence Induction.

The results of the MH risk assessment and anaesthetic assessment are then combined to plan patient care. If a patient has a high anaesthetic and/or MH risk, they will not be suitable for the ketamine sedation protocol and may warrant intubation. All high-risk cases would be discussed with the senior RFDSSE Consultant on call and/or the State Retrieval Consultant at ACC to agree the best management strategy.

Figure 2 outlines our standardised pharmacological sedation protocol. If a decision to use either physical or pharmacological restraint is taken, then the least restrictive intervention should be followed at all times. Sedation depth is then titrated in relation to a sedation score.[7]

Study design and participants

This was a retrospective cohort study. All aeromedical transfers performed by the RFDSSE retrieval service between 1 January 2011 and 31 December 2022 were screened through the electronic case database. Those recorded as MH transfers as per ICD-10 codes F20-F33 were selected for review. All adult and paediatric MH transfers that received any pharmacological sedation met eligibility criteria. Medications administered orally included lorazepam, diazepam and olanzapine; intramuscular (IM) medications droperidol and ketamine and intravenous (IV) medications midazolam, droperidol, ketamine and propofol. Such treatments' alignment with protocol is demonstrated in figure 2.

Clinical transfer records of AMH patients were then reviewed individually. Patient demographics (age, sex), mental health risk assessment score, active drug intoxication and transfer duration (minutes) were abstracted from the record, as well as pharmacological sedation administered (type and method of delivery), complications (any, severe) and intubation status. Patients who were actively drug intoxicated were excluded from further analysis.

Severe complications were defined as hypoxia (any documented pulse oximetry reading <92%),[8] hypotension (any documented systolic blood pressure (SBP) <90 mm Hg), bradycardia (any documented heart rate (HR) <50 bpm), airway compromise, cardiac arrest, and 'other', which included pneumothorax, seizure, ongoing agitation limiting ability to manage patients and the presence of a police officer on board for crew safety. Non-severe complications were tachycardia (HR >110 bpm) and hypertension (SBP >150 mm Hg) that did not require any intervention by the retrieval team. Complications were only recorded if they occurred prior to handover of the patient; no follow-up beyond handover was undertaken.

As education on protocol procedure was rolled out prior to the formal introduction of the protocol, patients were stratified into those whose treatment aligned with the protocol (OnP) and those that did not (OffP). Therefore, patients treated prior to introduction of the protocol were included in the OnP group if treatment received aligned with the protocol while in development. This amounted to six OnP patients and four OffP patients prior to implementation. Incidence of complications and severe complications between the two groups was assessed.

Statistical analysis

The distribution of continuous variables (eg, age, transfer duration) was explored using the one-sample Kolmogorov-Smirnov test. Where data were significantly skewed, central tendency was reported as median (IQR), rather than mean (SD). For continuous data, the difference between groups (OnP and OffP) was analysed using Student's t-tests where data were normally distributed and using the Mann-Whitney U when skewed. Associations between categorical variables (eg, alignment with protocol and sex) were explored using χ^2 analyses. Analysis also included the incidence of severe complications stratified by mental health risk assessment and medications given. Where cell sizes were small, the Fisher's exact test (FET) p value is reported. All analyses were conducted using IBM SPSS V.28.0, and p value <0.05 is considered indicative of statistical significance.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

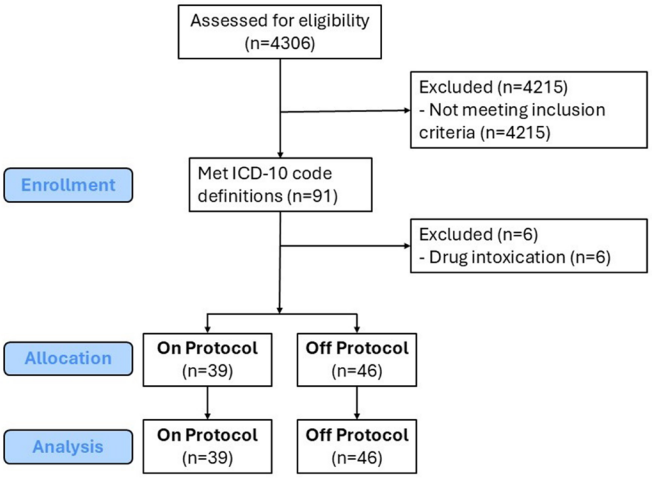

Figure 3 Case screening and group allocation. ICD-10/International Statistical Classification of Diseases and Related Health Problems 10th Revision.

Table 1 Patient characteristics of acutely unwell mental health patients requiring aeromedical transfer by RFDSSE between 1 January 2011 and 31 December 2022 presented by use of protocol

Demographics	Total N=85	On protocol n=39	Off protocol n=46	P value
Age, median (IQR)	37 (28–51)	38 (27–45)	36 (28–53)	0.47
Range	12–100	13–69	12–100	
Male, n (%)	59 (69.4)	27 (69.2)	32 (69.6)	0.97
Transfer duration minutes, mean (SD)	159 (63)	144 (67)	172 (56)	0.044
Range	30–390	30–280	80–390	
Mental health risk assessment, n (%)				
Low-medium risk	16 (18.8)	11 (28.2)	5 (10.9)	FET 0.05
High risk	47 (55.2)	20 (51.3)	27 (58.7)	FET 0.52
Not recorded	22 (25.9)	8 (20.5)	14 (30.4)	FET 0.33

NB. Data missing for age for n=4.
FET, Fisher's exact test; RFDSSE, Royal Flying Doctor Service South Eastern Section.

RESULTS

A total of 91 patients met the inclusion criteria, of which 6 were excluded from further analysis due to active drug intoxication (n=5 OnP, n=1 OffP). Of the remaining 85 patients, 39 (45.9%) were identified as OnP and 46 (54.1%) OffP (figure 3). While age and sex were comparable between both groups, transfer duration was significantly shorter in the OnP group (table 1). All transfers were from rural clinics or hospitals to other hospitals; no prehospital cases were recorded.

The overall rate of complications was 41.2% and was significantly lower in the OnP group (25.6% vs 54.3%, a difference of 28.7% (95% CI 7.8% to 46.2%), p=0.007; table 2). The overall rate of severe complications was 22.4% and again was significantly lower in the OnP group (5.1% vs 37.0%, difference of 31.8% (95% CI 14.7% to 46.7%), p<0.001; table 2). Of severe complications, the most encountered was hypotension, followed by hypoxia and need for airway manoeuvres or interventions. Of patients experiencing severe complications, 95% required intervention (IV fluids, vasopressors, intercostal chest drain, airway manoeuvres or intubation). No patients had reported nausea, vomiting, rigidity, laryngospasm or clinically significant secretions.

Medications administered in both groups are demonstrated in table 3. Ketamine use was comparable between the two groups. All but two of the OffP group who received ketamine were co-administered midazolam. One patient received a total of 30 mg IM droperidol, while another remained in a rural hospital overnight sedated using a ketamine infusion, not in alignment with the protocol. Midazolam use had a severe complication rate of 30.3% (n=10/85). All midazolam patients were considered OffP. Total intubated patients were 9/85 (10.6%), all of which were in the OffP group. Significantly more patients in the OnP group received oral medications and/or IM droperidol, with only one patient having any severe complications.

There was no statistically significant difference in mental health risk assessment scores between groups (p=0.11) and no statistically significant relationship between level of mental health risk and incidence of complications, except for a higher rate of complications where MH risk was not recorded (FET p=0.031; table 4). While the proportion of severe complications increased from 12.5% (n=2) for those deemed low-medium to 23.4% (n=11) for high risk and 27.3% (n=6) for those with no risk documentation, this was not statistically significant (p=0.54).

DISCUSSION

The proportion of AMH patients with severe complications was significantly lower when treatment aligned with the standardised mental health transfer protocol (OnP). This was also true for complications overall, regardless of severity. Just over half (54.3%) of OffP patients experienced a complication, while the rate among OnP patients was only one in four patients (25.6%). When focusing on severe complications, this difference was even greater—approximately a third of the OffP patients (37.0%) versus only two of the OnP patients (5.1%, p<0.001). Subgroup analysis by medications administered retains this lower severe complication rate, demonstrating that OnP patients had a lower rate of severe complications than OffP patients. The number of intubations in our study was low, but there was a significantly higher incidence of complications in this patient group.

This study is of similar size and methodology to recent studies in the area.[4 5] However, our study aimed to focus on the use of a structured sedation protocol for the transport of AMH patients specifically, rather than ABD of any aetiology. To the authors'

Table 2 Complications experienced by acutely unwell mental health patients during aeromedical transfer presented by use of protocol

	Total N=85 n (%)	On protocol n=39 n (%)	Off protocol n=46 n (%)	Difference (95% CI)	P value
Any complication	**35 (41.2)**	**10 (25.6)**	**25 (54.3)**	**28.7 (7.8 to 46.2)**	**0.007**
Tachycardia	*12 (14.1)*	*4 (10.3)*	*8 (17.4)*	7.1 (–8.6 to 21.8)	0.35
Hypertension	*11 (12.9)*	*6 (15.4)*	*5 (10.9)*	4.5 (–10.1 to 20.1)	0.54
Nausea/vomiting	*0*	*0*	*0*	–	n/a
Secretions	*0*	*0*	*0*	–	n/a
Severe complications	**19 (22.4)**	**2 (5.1)**	**17 (37.0)**	**31.8 (14.7 to 46.7)**	**<0.001**
Hypotension	*7 (8.2)*	*1 (2.6)*	*6 (13.0)*	10.5 (–2.2 to 23.3)	FET 0.12
Hypoxia	*6 (7.1)*	*1 (2.6)*	*5 (10.9)*	8.3 (–4.0 to 20.7)	FET 0.21
Airway compromise	*3 (3.5)*	*0*	*3 (6.5)*	6.5 (–3.4 to 17.5)	FET 0.25
Seizure	*1 (1.2)*	*0*	*1 (2.2)*	2.2 (–7.0 to 11.3)	FET 1.0
Cardiac arrest	*0*	*0*	*0*	–	n/a
*Other**	*4 (4.7)*	*0*	*4 (8.7)*	8.7 (–1.7 to 20.3)	FET 0.12

Complications included hypotension/hypertension, tachycardia/bradycardia, hypoxia, nausea/vomiting, rigidity, increased secretions, laryngospasm.
Severe complications were defined as hypoxia, hypotension, airway compromise, seizure, cardiac arrest.
*Other complications included ongoing agitation requiring active physical restraint and the presence of a police officer on board, pneumothorax and seizure.
FET, Fisher's exact test.

Table 3 Treatment administered and severe complications experienced by acutely unwell mental health patients during aeromedical transfer, presented by use of protocol

	Total N=85 n (%)	On protocol n=39 n (%)	Off protocol n=46 n (%)	Difference (95% CI)	P value
Orals*±IM/IV droperidol	20 (23.5)	19 (48.7)	1 (2.2)	46.5 (29.1 to 61.7)	<0.001
Severe complications	*1 (5.0)*	*1 (5.3)*	*0*	*5.3 (–74.2 to 24.6)*	1.0
IM/IV ketamine	48 (56.5)	20 (51.3)	28† (60.9)	9.6 (–11.1 to 29.3)	0.37
severe complications	*9 (18.8)*	*1 (5.0)*	*8 (28.6)*	*23.6 (0.7 to 42.5)*	FET 0.061
IM/IV midazolam	33 (38.8)	0	33 (71.7)	71.7 (54.9 to 82.7)	<0.001
Severe complications	*10 (30.3)*	–	*10 (30.3)*	*n/a*	–
Intubated	9 (10.6)	0	9 (19.6)	19.6 (6.9 to 33.2)	FET 0.003
Severe complications	*6 (66.7)*	–	*6 (66.7)*	*n/a*	–

*Oral medications included olanzapine (10–20 mg), diazepam (10–20 mg) and lorazepam (2 mg).
†All OffP patients given ketamine received it in combination with off-protocol medications.
FET, Fisher's exact test; IM, intramuscular; IV, intravenous.

knowledge, the only prior research regarding sedation for AMH patients was a case series of 19 patients.[3] Other studies have addressed the use of ketamine sedation for ABD but have not selected out pure AMH patients and focused on adverse event rates, as our study sought to.

Patients who received midazolam had the highest rate of severe complications of any IV/IM medication (30.3%). This is in keeping with findings in which drug-related adverse effects were shown to be more common in patients who received midazolam (28%) versus droperidol (6%).[9] In the six patients who received midazolam monotherapy, those who received<6 mg/hour remained agitated, while those who received >6 mg/hour all experienced severe complications. From reviewing this small subgroup, midazolam monotherapy does not appear suitable for mental health sedation. In OffP patients who received midazolam in addition to ketamine sedation, doses as low as 2.5 mg (midazolam) led to airway compromise requiring intervention.

Ketamine sedation had the lowest severe complication rate of any IV medication given: 5.0% on protocol and 28.6% off protocol (FET 0.061). Ketamine infusions have been shown to have a severe adverse event rate of 38% (n=25/66).[4] Use of our protocol led to a much lower rate of adverse events. The principal difference between these is our exclusion of patients with presentations thought to be due to drug intoxication, which may suggest such patients are at higher risk of complications.

Reasons for deviation from protocol were not clear from patient notes. It is likely that clinician familiarity with medications contributed. Five transferred patients were aged 16 and under (mean age 14). A 12-year-old patient (the only patient <16 years in the OffP group) was treated solely with aliquots of midazolam, requiring jaw thrust and administration of 50% oxygen. In the OnP group, three paediatric patients received ketamine infusions with no serious complications. Although ketamine has been well adopted for the care of paediatric patients requiring procedural sedation, this is the first report to the authors' knowledge of its use to sedate paediatric AMH patients for aeromedical transfer.

Of the patients who required intubation, we observed a high rate of severe complications (66.7%), akin to that demonstrated in another recent study.[4] This is in contrast with a standard ED Rapid Sequence Induction which has a reported complication rate of 10–30%.[10] This dispels the conventional notion that intubating an unwell mental health patient in a remote or rural environment for aeromedical transfer is safe practice and suggests intubation in this patient group should be considered a high-risk procedure and alternate strategies considered. Eight of the nine intubations in our study were undertaken before the arrival of RFDSSE, at the request of an off-site non-RFDSSE clinician. Indication for intubation was not clear from available documentation but may include remote supervising or hospital clinician preference. All intubations occurred since 2020, sometime after protocol implementation, reflecting that awareness of RFDSSE capability to transfer on ketamine infusions may have been limited. A previous consensus statement on ketamine sedation for similar patients has been produced,[7] but our findings support wider adoption or commissioning of a state-wide protocol in New South Wales.

Table 4 Mental health risk assessment categories and complications experienced by acutely unwell mental health patients during aeromedical transfer, presented by use of protocol

	Total N=85 n (%)	On protocol n=39 n (%)	Off protocol n=46 n (%)	Difference (95% CI)	P value
Low-medium risk	16 (18.8)	11 (28.2)	5 (10.9)	17.3 (0.5 to 34.1)	FET 0.05
Complications	*6 (37.5)*	*3 (27.3)*	*3 (60.0)*	32.7 (–14.4 to 66.0)	FET 0.30
Severe complications	*2 (12.5)*	*0*	*2 (40.0)*	40.0 (1.7 to 76.9)	FET 0.08
High risk	47 (55.2)	20 (51.3)	27 (58.7)	7.4 (–13.2 to 27.3)	FET 0.52
Complications	*19 (40.4)*	*6 (30.0)*	*13 (48.1)*	18.2 (–9.8 to 41.8)	0.21
Severe complications	*11 (23.4)*	*2 (10.0)*	*9 (33.3)*	23.3 (–1.6 to 43.5)	FET 0.09
Not recorded	22 (25.9)	8 (20.5)	14 (30.4)	9.9 (–8.9 to 27.3)	FET 0.33
Complications	*10 (45.5)*	*1 (12.5)*	*9 (64.3)*	51.8 (8.8 to 73.7)	FET 0.031
Severe complications	*6 (27.3)*	*0*	*6 (42.9)*	42.9 (4.0 to 67.4)	FET 0.051

FET, Fisher's exact test.

Limitations

This was a retrospective study covering a period of 11 years during which standard practice may have changed, a potential confounding factor. RFDSSE's mental health risk assessment tool has not yet been validated, and while the sedation protocol was well defined, sedation practice among patients in the OffP group varied considerably, with some groups too small for statistically significant analysis. For example, one patient received propofol sedation. This study may therefore not be powered to identify the optimal sedation regimen for AMH patients, an outcome outside the scope or aims of the study. The small sample precludes a multivariable analysis, and confounding factors could not be adjusted for. A prospective, blinded randomised controlled trial would reduce bias in answering our study question, although given the ongoing development in standard care, this would be challenging to undertake.

Transfer duration was significantly shorter in the OnP group (mean time of 148 min vs 172 min, p=0.044). This may suggest fewer complications occurred in the OnP group due to shorter transfer times. However, in a post hoc analysis, while there was a statistically significant relationship between longer transfer times and all complications, this relationship did not hold true for severe complications. It is unknown if longer term complications occurred as no follow-up was done beyond patient handover at the receiving hospital. Additionally, undocumented patient factors may have led to differences between OnP or OffP results. Our study was conducted on patients undergoing retrieval by fixed wing aircraft, and results may not be generalisable to the in-hospital population or those transported by other means.

Implications/recommendations

The use of a structured sedation protocol which includes use of ketamine sedation to manage AMH patients during aeromedical transfer is recommended as it is significantly safer than previous practice. Protocolised treatment resulted in fewer complications, reduced need for intubation and receiving intensive care unit beds. We strongly advise against the use of midazolam for the management of AMH patients during transfer as this was associated with the highest severe complication rate. Further research into optimal sedation strategies for AMH patients is recommended.

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Contributors JL: Guarantor, conceived and designed analysis, collected the data and wrote the paper (joint first authorship with AP, contributed significantly to the writing of the manuscript). AP: Collected the data and wrote the paper (joint first authorship with JL, contributed significantly to the writing of the manuscript). PB: Conceived and designed analysis. EW: Contributed data or analysis tools. GML: Contributed data or analysis tools and performed the analysis.

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Patient consent for publication Not applicable.

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