Adverse events and outcomes of procedural sedation and analgesia in major trauma patients

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ABSTRACT

Context: Trauma patients requiring procedural sedation and analgesia (PSA) may have increased risk of adverse events (AEs) and poor outcomes. Aims: To determine the incidence of AEs in adult major trauma patients who received PSA and to evaluate their postprocedural outcomes. Settings and Design: Retrospective analysis of adult patients (age > 16) who received PSA between 2006 and 2014 at a Canadian academic tertiary care center. Materials and Methods: We compared the incidence of PSA-related AEs in trauma patients with nontrauma patients. Postprocedural outcomes including Intensive Care Unit admission, length of hospital stay, and mortality were compared between trauma patients who did or did not receive PSA. Statistical Analysis Used: Descriptive statistics and multivariable logistic regression. Results: Overall, 4324 patients received PSA during their procedure, of which 101 were trauma patients (107 procedures). The majority (77%) of these 101 trauma patients were male, relatively healthy (78% with American Society of Anesthesiologists Physical Status [ASA-PS] 1), and most (85%) of the 107 procedures were orthopedic manipulations. PSA-related AEs were experienced by 45.5% of the trauma group and 45.9% of the nontrauma group. In the trauma group, the most common AEs were tachypnea (23%) and hypotension (20%). After controlling for age, gender, and ASA-PS, trauma patients were more likely than nontrauma patients to develop hypotension (odds ratio 1.79; 95% confidence interval 1.11-2.89). Conclusion: Although trauma patients were more likely than nontrauma patients to develop hypotension during PSA, their outcomes were not worse compared to trauma patients who did not have PSA.

Key Words: Analgesia, outcomes, procedural, retrospective, sedation, trauma

INTRODUCTION

Adverse events (AEs) related to procedural sedation and analgesia (PSA) in adult emergency department (ED) patients have been reported to a range from nil to over 60%.1-8 Patients with major (i.e., multisystem) trauma may have physiological challenges that increase their risk of AEs during PSA.9 It is unknown whether trauma patients are more likely to experience PSA-related AEs compared with the general ED population. This study sought to determine whether trauma patients receiving PSA were more likely than the general ED population to experience AEs, and to compare postprocedural outcomes among trauma patients who did or did not receive PSA.

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MATERIALS AND METHODS

Approval for this study was obtained from the Nova Scotia Health Authority Research Ethics Board in Halifax, Nova Scotia, Canada. This study is a retrospective case series that was conducted at an academic tertiary care center in Halifax, Nova Scotia using data from the Nova Scotia Trauma Registry (NSTR) and the Dalhousie Department of Emergency Medicine Procedural Sedation Registry (EDPSR). This center is a Level One Trauma Centre and the primary referral hospital for the province of Nova Scotia (population 940,592). A dedicated PSA patient care record (EDPSR) was introduced in 2003 to assist with patient monitoring and medication administration during PSA, and to document each case of PSA performed in the ED to verify the safety and effectiveness of this practice. Clinical and procedural data on all adult patients who undergo PSA in the ED are captured by dedicated department-based advanced care paramedics in the EDPSR, with approximately 900 PSAs conducted per year.[8]

The NSTR is a population-based registry that has been collecting detailed information on all major traumas in the province of Nova Scotia since 1994. Criteria for inclusion in the NSTR are any traumas with an Injury Severity Score (ISS) >12 and an appropriate International Classification of Disease External Cause of Injury Code. Penetrating injury cases with an ISS ≥9 are also included in the NSTR, as well as any trauma team activation (TTA) regardless of ISS, and any injuries resulting in death in the ED. Patients who require TTA are seen by a trauma team leader and a resident trauma team leader, as well as multiple specialties and staff members who are activated if one or more criteria for TTA are met.[10] For the purpose of this study, the terms “major trauma” and “trauma” are used interchangeably. This study was performed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting observational studies.[11]

Data were collected from the EDPSR for all adult patients (age >16 years) who required PSA as part of their procedure between January 1, 2006 and March 31, 2014. Following the initial identification of study participants, a co-investigator manually reviewed their medical record, and patients who met eligibility criteria were retained. Cases that were identified from the EDPSR were matched with patient records from the NSTR. We also collected data on all remaining adult trauma patients in the NSTR during the study period in order to compare their outcomes with trauma patients who received PSA. Data were not imputed if missing, and patients with missing data were excluded from analysis. Data abstracted from the NSTR and EDPSR were collated into a standardized Microsoft® Access 2003 (Redmond, Washington, USA) database, created for the purpose of this study.

To minimize the risk of bias, all information for the study was abstracted without modification from the NSTR and EDPSR. Data elements collected from the NSTR included patient age, gender, ISS, and Abbreviated Injury Scale (AIS) head score. From the EDPSR, we collected American Society of Anesthesiologists Physical Status (ASA-PS) level, procedure type, and the occurrence of the following intra-procedural AEs: Hypoxia (oxygen saturation ≤90%), hypotension (systolic blood ≤100 mm Hg), bradycardia (heart rate ≤50 beats/min), tachycardia (heart rate ≥120 beats/min), bradypnea (respiratory rate ≤10 respirations/min), and tachypnea (respiratory rate ≤20 respirations/min). Some patients who received PSA may have experienced more than one AE, or may have received PSA more than once during multiple procedures for the same case of major trauma. If a patient had more than one major trauma within a 2 year period and required PSA for their procedure, we only included data from their initial traumatic incident. We did not address the medication regimen in this study as our primary objective was the global incidence of AEs during PSA.

The NSTR and the EDPSR both have quality control procedures in place to ensure accurate, reliable, and complete data entry, with the NSTR utilizing dedicated support staff for the purposes of system performance evaluation and improvement. Any duplicate records were excluded from analysis. The sample size for this study was dependent on the number of trauma patients requiring PSA that were captured in both databases. This study is observational, thus, we did not perform a power analysis.

The primary outcome measure for this study was the incidence of any AE in patients who received PSA as part of their procedure. Secondary outcome measures included the following postprocedural outcomes in major trauma patients: In-hospital mortality, patient length of stay (LOS) in-hospital, admission to the Intensive Care Unit (ICU), ICU LOS, admission to the Intermediate Care Unit (IMCU), and IMCU LOS.

Descriptive statistics including means, standard deviations (SDs), proportions, medians, and ranges were used to characterize patient outcomes. For continuous data, Welch’s t-test was used to evaluate for differences where the assumption of normality was satisfied. Where the assumption of normality was not satisfied, we used nonparametric methods for analysis. For nominal data, we used Fisher’s test to evaluate for associations between the different groups.

To determine the importance of traumatic injury, a multivariable logistic regression model was used to investigate the association between PSA and intra-procedural AEs in trauma and nontrauma patients who underwent PSA as part of their ED care. Variable selection for the logistic regression models was determined a priori based on clinical experience, expert opinion, and available data, and included age, gender, and ASA-PS level.

In order to determine the impact of PSA on outcomes in major trauma patients, we employed a second multivariable logistic regression analysis. We examined all trauma cases during the study period and compared outcomes between the patients who received PSA with those who did not, to determine if there was an association with in-hospital mortality, ICU admission, IMCU
admission or hospital admission. To assess the goodness-of-fit of the models, we report the Hosmer-Lemeshow test result using a P > 0.05 as a satisfactory fit. All statistical tests were performed with the R-statistical software package (V3.1.2 “Pumpkin Helmet”; R Foundation for Statistical Computing, Vienna, Austria) using the RStudio GUI (V0.98.932) and performed at a confidence level of 95%.

**RESULTS**

A flow diagram outlining the study design is shown in Figure 1. There were no missing data elements for any participants in this study, and no patients were lost to follow-up. Overall, 4324 patients received PSA during the study period. Of patients who received PSA, 101 trauma patients had a total of 107 procedures (5 patients with two procedures each during same trauma, 1 patient with two procedures >2 years apart). There were 3647 cases of adult trauma captured in the NSTR during the study. Demographics and characteristics of the study population are shown in Table 1. Trauma patients who received PSA tended to be middle-aged (mean age 41.2 ± 17.8 years), male (78, 77%), relatively healthy (79 with ASA-PS I, 78%), and most required an orthopedic procedure (91, 85%).

The overall incidence of AEs in patients who received PSA was 45.5% (46/101) in the trauma group and 45.9% (1938/4223) in the nontrauma group [Table 2]. Tachypnea (23/101, 23%) and hypotension (20/101, 20%) were the most common AEs recorded in the trauma group. After adjusting for patient age, gender, and ASA-PS level, the only AE observed to be statistically significant was hypotension (20% trauma vs. 16% nontrauma; odds ratio [OR] 1.79, 95% confidence interval [CI] 1.11-2.89).

Table 3 compares postprocedural patient outcomes in trauma patients who received PSA with outcomes in trauma patients who did not receive PSA. Among trauma patients who received PSA, 2% (2/101) died in-hospital and 81% (82/101) were admitted to a high-intensity in-hospital unit (ICU 10, 10%; IMCU 72, 71%). By comparison, of the 3546 trauma patients who did not receive PSA as part of their procedure, 11% (405/3546) died in-hospital and 98% (3480/3546) were admitted to a high-intensity in-hospital unit (ICU 1029, 29%; IMCU 2451, 69%). The average hospital LOS for trauma patients who received PSA was 10.5 days (SD 9.8 days) vs. 13.4 days (SD 12.8 days) for those who did not receive PSA.

**Table 1: Demographics and characteristics of study population**

| Characteristic | Trauma (n = 101) | Nontrauma (n = 4223) | Trauma, no PSA (n = 3546) |
|---------------|-----------------|----------------------|-------------------------|
| Male, n (%)   | 78 (77)         | 2039 (48)            | 2627 (74)               |
| Ages (SD)     | 42 ± 17.8       | 50.2 ± 26.1          | 48.7 ± 22.4             |
| ASA-PS, n (%) | I               | 79 (78)              | 2776 (66)               |
|               | II              | 20 (20)              | 1183 (28)               |
|               | III or less     | 2 (2)                | 185 (4)                 |
|               | Unknown         | 0 (0)                | 79 (2)                  |
| ISS, n (%)    | 0-15            | 44 (44)              | 1086 (31)               |
|               | 16-30           | 47 (46)              | 2069 (58)               |
|               | 31-45           | 10 (10)              | 54 (2)                  |
|               | Not assessed    | 0 (0)                | 337 (9)                 |
| Procedure*    | Orthopedic      | 91 (88)              | 2969 (69)               |
|               | Chest tube      | 15 (15)              | 128 (3)                 |
|               | Imaging         | 1 (1)                | 19 (1)                  |
|               | Other†          | 0 (0)                | 133 (3)                 |

*107 PROCEDURES IN 101 TRAUMA PATIENTS; INCLUDED ELECTRICAL CARDIOVERSION, INCISION, AND DRAINAGE; PROCEDURE TYPE AND ASA-PS UNAVAILABLE FOR NON-PSA PATIENTS. ISS UNAVAILABLE FOR NONTRAUMA PSA PATIENTS. ASA-PS: AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS; ISS: INJURY SEVERITY SCORE; PSA: PROCEDURAL SEDATION AND ANALGESIA; SD: STANDARD DEVIATION

**Table 2: Adverse events during PSA in trauma and nontrauma patients**

| Adverse event | Trauma (n = 101) | Nontrauma (n = 4223) | Crude OR (95% CI) | Adjusted OR (95% CI) | Adjusted P |
|---------------|-----------------|----------------------|-----------------|---------------------|-----------|
| Hypoxia       | 1 (1)           | 75 (2)               | 0.52 (1.00)     | 0.64 (0.94-2.68)    | 0.635     |
| Hypotension   | 20 (20)         | 671 (16)             | 1.45 (0.234)    | 1.79 (1.12-2.89)    | 0.023     |
| Bradycardia   | 2 (2)           | 147 (3)              | 0.53 (0.287)    | 0.48 (0.12-1.96)    | 0.248     |
| Tachycardia   | 7 (7)           | 423 (10)             | 1.64 (0.314)    | 1.68 (0.31-2.49)    | 0.326     |
| Bradypnea     | 5 (5)           | 333 (3)              | 1.57 (0.392)    | 1.65 (0.42-4.19)    | 0.343     |
| Tachycardia†  | 23 (23)         | 725 (17)             | 1.47 (0.219)    | 1.56 (0.93-2.67)    | 0.069     |

*Some patients experienced > one adverse event; data adjusted for age, gender, and ASA-PS level. OR: Odds ratio; CI: Confidence interval; ASA-PS: American Society of Anesthesiologists Physical Status; PSA: Procedural Sedation and Analgesia

**Table 3: Postprocedural outcomes in trauma patients who did or did not receive PSA**

| Postprocedural outcome | Trauma patients (n = 101) | No PSA (n = 3546) |
|------------------------|---------------------------|-------------------|
| In-hospital mortality, n (%) | 2 (2)                      | 405 (11)           |
| Admitted to hospital, n (%)  | 99 (98)                    | 3259 (92)          |
| Hospital LOS (average±SD) | 10.5 (9.5)                 | 15.3 ± 13.7        |
| Admitted to ICU, n (%)      | 20 (20)                    | 1029 (29)          |
| ICU LOS (average±SD)       | 6.47 ± 2                   | 4.2 ± 13.6         |
| Admitted to IMCU, n (%)     | 72 (72)                    | 245 (69)           |
| IMCU LOS (average±SD)      | 4.15 ± 2                   | 6.7 ± 24.3         |

P: PSA PROCEDURAL SEDATION AND ANALGESIA; LOS: LENGTH OF STAY; SD: STANDARD DEVIATION; ICU: INTENSIVE CARE UNIT; IMCU: INTERMEDIATE CARE UNIT
The result of the logistic regression measuring the impact of PSA on postprocedural outcomes in the trauma patient population is shown in Table 4. Compared with trauma patients who did not receive PSA, trauma patients who received PSA were less likely to die in hospital (OR 0.25, 95% CI 0.06-1.04) or to be admitted to an ICU (OR 0.25, 95% CI 0.13-0.49), and more likely to be admitted to hospital (OR 5.11, 95% CI 1.24-20.99) and to an IMCU in particular (OR 2.72, 95% CI 1.76-4.20). These effects were all statistically significant.

**DISCUSSION**

The overall incidence of AEs during PSA was 45.5% in trauma patients and 45.9% in nontrauma patients. Tachypnea and hypotension were the two most common AEs observed in the trauma group. However, after adjusting for patient age, gender, and ASA-PS level, the only AE associated with PSA in trauma patients was hypotension. Despite having increased hypotension, it did not seem to impact patient outcome as in-hospital mortality in trauma patients who received PSA was less than that observed in trauma patients who did not receive PSA, a finding also true for admission to an ICU. This effect was maintained even when correcting for age, AIS head score, and ISS score. This implies that PSA in the major trauma patient is generally safe as currently practiced within our institution.

AEs during PSA have been reported in the literature to include apnea, aspiration, bronchospasm, cardiovascular instability, dysrhythmias, emesis, hypotension, hypoxia, laryngospasm, respiratory compromise, and stridor.[12-14] The incidence of these AEs is likely associated with patient-specific factors (e.g., age, injury, illness, and medications), PSA provider skill and medication used, and the intensity of patient monitoring.[13,14] We were surprised to find that the incidence of AEs during PSA was essentially the same in the trauma (45.5%) and nontrauma (45.9%) groups. We observed a higher rate of hypotension than previously reported in studies of PSA in the ED. Our definition for hypotension as any SBP <100 mm Hg differs from previous reports of PSA in the ED which defined hypotension as a systolic pressure of <85 mm Hg in any patient who had a preprocedural systolic pressure of 100 mm Hg or greater,[13] as a systolic pressure <80 mm Hg,[15] as a systolic pressure <90 mm Hg,[16] or as a 20% decrease in mean arterial blood pressure from preprocedural levels.[8] These previous studies observed hypotension in 0-1.6% of patients.

Current PSA practice at our institution is to define any systolic blood pressure (SBP) <100 mm Hg as an AE. This is supported by evidence that a single episode of ED hypotension (SBP <100 mm Hg) confers significantly increased risk of mortality during hospitalization, and that risk of death increases with more severe and prolonged hypotension.[17,18] There are also reports that a systolic pressure below 110 mm Hg is associated with increased mortality regardless of age in adult patients with blunt trauma or penetrating trauma.[18,19] We believe defining hypotension as <100 mm Hg is a reasonable compromise between the cut-offs of 85 mm Hg for the general PSA patients and 110 mm Hg for trauma patients.

Although our analysis focused on the global incidence of PSA-related AEs in the ED, it is important to recognize that medications used during PSA may affect patient physiology, especially in critically ill patients. Some PSA agents like propofol can cause a reduction of sympathetic output from the central nervous system, thereby causing some degree of bradyarrhythmia and hypotension.[13] In addition to reduced sympathetic output, each class of PSA agents (opiates, sedatives, dissociative agents, and reversal agents) has a wide range of effects on the cardiovascular system that could result in AEs like hypotension or dysrhythmias.[16,14] Patient factors can also influence the pharmacologic response to a number of the medications used for PSA. A careful review of patient history including drug and food allergies can reveal conditions that may promote susceptibility to an AE. The existence of significant comorbidities such as coronary artery disease or congestive heart failure may preclude the performance of PSA in the ED altogether.

In this study, we found that major trauma patients were more likely to experience hypotension than the general ED patient population (20% trauma vs. 16% nontrauma; OR 1.79, 95% CI 1.11-2.89). Although our results show that there was no increased mortality in the trauma group that received PSA, hypotension in trauma patients (especially those with traumatic brain injuries) has been associated with poor patient outcomes.[18-21] This highlights a potential concern and a point of caution for physicians who make the decision to administer PSA in major trauma patients. Our results also demonstrate that trauma patients who received PSA were more likely to be admitted to hospital or an IMCU than trauma patients who did not receive PSA, but less likely to be admitted to an ICU or die in hospital. Post-hoc subgroup analysis indicated that this is true even after we removed patients who died in hospital from the analysis.

This study has the limitations of a retrospective study on an existing dataset and cannot be used to imply causality. Patients were not randomized and there were potential confounders including the fact that trauma patients receiving PSA were more likely to have orthopedic injuries as their major problem, and...
thus less likely to go home or die in hospital. The results of this study are dependent on accurate reporting by physicians, and information collected in the context of an emergency situation may not be as comprehensive as information collected for routinely scheduled hospital procedures. It is likely that physician preference was a key variable in this study. Although the administration of PSA follows a standardized approach with all paramedics trained to perform and monitor PSA in the ED, the decision of which patients receive PSA is not standardized and is determined on a case by case basis by the attending physician/trauma team leader. Trauma team leaders may have been more likely to perform PSA in trauma patients they deemed would be able to tolerate the procedure. Furthermore, trauma patients (with more potential for multi-organ injury) are managed by a multidisciplinary team with special emphasis and bias toward resuscitation, while the nontrauma PSA patient is more likely to have their injury as their only issue. This may affect the generalizability of our results to other institutions. Our finding that trauma patients who received formal PSA, despite having increased incidence of intra-procedure hypotension, had reduced mortality, ICU admission rate, and hospital LOS supports this hypothesis. Although hypotension in blunt trauma patients is generally associated with poor outcomes, it did not seem to impact patient outcomes in our study population.

In summary, the incidence of AEs in trauma patients undergoing PSA was 45.5% in our study. Although these patients were less likely to die in hospital or be admitted to the ICU compared with trauma patients who did not receive PSA, they were more likely to be admitted to an IMCU or admitted to the hospital overall. More research is necessary to clarify the optimal practice with regard to PSA in major trauma patients.

Acknowledgment
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Conflicts of interest
There are no conflicts of interest.

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# STROBE checklist[111]

## STROBE statement - checklist of items that should be included in reports of observational studies

| Item | Item number | Recommendation | Page |
|------|-------------|----------------|------|
| Title and abstract | 1 | (a) Indicate the study’s design with a commonly used term in the title or the abstract<br>(b) Provide in the abstract an informative and balanced summary of what was done and what was found | 1 |
| Introduction | 2 | Explain the scientific background and rationale for the investigation being reported | 1 |
| Background/rationale | 3 | State specific objectives, including any prespecified hypotheses | 1 |
| Objectives | 4 | | 2 |
| Methods | 5 | | 2 |
| Study design | 6 | (a) Cohort study: Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>Case-control study: Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>Cross-sectional study: Give the eligibility criteria, and the sources and methods of selection of participants<br>(b) Cohort study: For matched studies, give matching criteria and number of exposed and unexposed<br>Case-control study: For matched studies, give matching criteria and the number of controls per case | 2 |
| Participants | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 2, 3 |
| Variables | 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 2, 3 |
| Data sources/measurement | 9 | Describe any efforts to address potential sources of bias | 2 |
| Bias | 10 | Explain how the study size was arrived at | 2 |
| Study size | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 2, 3 |
| Quantitative variables | 12 | (a) Describe all statistical methods including those used to control for confounding<br>(b) Describe any methods used to examine subgroups and interactions<br>(c) Explain how missing data were addressed<br>(d) Cohort study: If applicable, explain how loss to follow-up was addressed<br>Case-control study: If applicable, explain how matching of cases and controls was addressed<br>Cross-sectional study: If applicable, describe analytical methods taking account of sampling strategy<br>(e) Describe any sensitivity analyses | N/A |
| Statistical methods | 13 | (a) Report numbers of individuals at each stage of study - e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed<br>(b) Give reasons for nonparticipation at each stage<br>(c) Consider use of a flow diagram | 3, Table 1<br>Figure 1 |
| Descriptive data | 14 | (a) Give characteristics of study participants (e.g., clinical demographic, clinical, and social) and information on exposures and potential confounders<br>(b) Indicate number of participants with missing data for each variable of interest<br>(c) Cohort study – Summarize follow-up time (e.g., average and total amount) | 3<br>N/A |
| Outcome data | 15 | Cohort study – Report numbers of outcome events or summary measures over time<br>Case-control study – Report numbers in each exposure category, or summary measures of exposure<br>Cross-sectional study – Report numbers of outcome events or summary measures | 3, 4 (Tables 2, 3)<br>N/A<br>N/A |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% CI). Make clear which confounders were adjusted for and why they were included<br>(b) Report category boundaries when continuous variables were categorized<br>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | 3, 4 (Tables 2-4)<br>N/A<br>N/A |
| Other analyses | 17 | Report other analyses done – e.g., analyses of subgroups and interactions, and sensitivity analyses | N/A |
| Results | 18 | Summarize key results with reference to study objectives | 4, 5 |
| Discussion | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 4, 5 |
| Key results | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 5 |
| Limitations | 21 | Discuss the generalizability (external validity) of the study results | 5 |
| Interpretation | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 5 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies. An explanation and elaboration of each checklist item and its relevance to transparent reporting is available on the websites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/. Information on the STROBE initiative is available at www.strobe-statement.org. STROBE: Strengthening the Reporting of Observational Studies in Epidemiology; CI: Confidence interval; N/A: Not available.

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