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SPECIAL FEATURE

Is There an Optimal Blood Pressure Target in Patients Presenting with Intracerebral Hemorrhage?

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Dr. Walter reports no financial relationships relevant to this field of study.

Spontaneous intracerebral hemorrhage (ICH) is an unfortunately common and devastating event. In 2010, an estimated 5.3 million patients worldwide experienced ICH.[1] Mortality at one month is approximately 40%, and survivors often exhibit significant long-term deficits, with independency rates of only 12-39%.[2] Between 50-70% of patients presenting with ICH have a history of arterial hypertension, making this the most common risk factor for ICH.[3] Furthermore, blood pressure often increases acutely in the setting of ICH.[4] Arguments have been made for and against the treatment of hypertension following ICH. Patients exhibiting chronic hypertension may demonstrate less ability to autoregulate cerebral blood flow, necessitating higher systemic blood pressure to maintain cerebral perfusion. There has been concern that aggressive blood pressure control following ICH may decrease blood flow to the ischemic penumbra.[3] On the other hand, aggressive blood pressure control may decrease hematoma expansion and cerebral edema.

Recently, two large randomized, controlled trials compared intensive blood pressure control with permissive hypertension in the setting of acute ICH.[5,6] The authors of the two trials reached seemingly differing conclusions, leading to confusion on how to best manage patients. Intensive Blood Pressure Reduction in Acute Cerebral Hemorrhage 2 (INTERACT2) was published in 2013 and Antihypertensive Treatment of Acute Cerebral Hemorrhage 2 (ATACH2) in 2016. Both studies were large, international, multicenter trials. The creators of both trials randomized patients with acute spontaneous ICH to a goal systolic

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blood pressure (SBP) of < 140 mmHg (intensive treatment) or < 180 mmHg (guideline or standard treatment). Results from INTERACT2 suggested that intensive blood pressure control improved functional outcomes at three months.[5] However, ATACH2 did not show any benefit, and a post-hoc analysis suggested intensive control increased adverse events.[6]

PATIENT SELECTION

Patients were eligible for inclusion in INTERACT2 (n = 2,839) if they presented with spontaneous ICH and a SBP 150-220 mmHg. In ATACH2, patients (n = 1,000) were enrolled if they exhibited at least one SBP reading ≥ 180 mmHg. Exclusion criteria in both studies were large ICH, deep coma (Glasgow Coma Scale < 6 for INTERACT2, < 5 for ATACH2), or a structural cerebral cause for the ICH (including trauma). Planned early surgery was an exclusion criterion for INTERACT2. The demographic and clinical characteristics of both populations were well matched across study groups and strikingly similar between studies. The mean age was just over 60 years, and about 60% of patients were male. Both studies recruited from more than 100 sites worldwide, with the majority of sites in Asian countries (~67% of patients in INTERACT2 were from China, and ~50% of patients in ATACH2 were from Asia). Central and East Asia demonstrate the highest incidence of ICH in the world.[1] The median National Institutes of Health Stroke Scale score (11) and hematoma volume (11 cm^3) were similar in both studies. Twenty-eight percent of patients in INTERACT2 experienced intraventricular extension of hemorrhage. In ATACH2, 25% of patients in the intensive treatment group and 29% of patients in the standard treatment group experienced intraventricular extension.

INTERVENTION

Researchers differed in their approaches in how to treat early and aggressive blood pressure. In INTERACT2, the goal was to reduce SBP to < 140 mmHg within one hour after randomization and to maintain this level for seven days for patients in the intensive treatment group. Patients in the guideline treatment group received treatment only if SBP was > 180 mmHg. Treatment could be initiated within six hours of symptom onset. In practice, the median time to first treatment was 4-4.5 hours, with nearly half of patients in the intensive treatment group not receiving any antihypertensives for more than four hours after symptom onset. Even with treatment, the goal SBP often was not achieved. Sixty-seven percent of patients in the intensive treatment group did not meet the SBP goal of < 140 mmHg within one hour. Despite these failures, at one hour there was a separation in mean SBP between treatment groups (150 mmHg in the intensive treatment group vs. 164 mmHg in the guideline treatment group).

ATACH2 was designed to offer even earlier and more aggressive blood pressure control. The treatment goal was to reduce SBP to 110-139 mmHg in the intensive treatment group and 140-179 in the standard treatment group. SBP goals were to be maintained for the first 24 hours after randomization, as opposed to INTERACT2, during which BP goals were maintained for seven days. The initial study design randomized patients who presented within three hours of symptom onset. This was extended to 4.5 hours after additional data became available that suggested a treatment effect of blood pressure control out to 4.5 hours and no difference in hematoma expansion between zero to three hours and three to 4.5 hours.[7] In practice, the median time to first treatment was three hours in both groups. Thus, in comparison to INTERACT2, in which nearly half the patients underwent randomization after four hours, all patients started treatment within 4.5 hours in ATACH2. The mean minimum SBP during the first two hours after randomization was 128.9 mmHg in the intensive treatment group and 141.1 in the standard treatment group. The treatment failure rate was much lower, with only 12.2% of patients in the intensive treatment group failing to achieve the SBP goal.

OUTCOMES

The primary outcome in both studies was death or severe disability. Severe disability was defined as a modified Rankin scale score of 3-6 in INTERACT2 and 4-6 in

Table 1: Comparison of Key Differences and Outcomes Between INTERACT2 and ATACH2

	Inclusion Criteria (Systolic Blood Pressure in mmHg)	Treatment Goals (Systolic Blood Pressure in mmHg)	Time to Randomization	Mean Systolic Blood Pressure (mmHg) Achieved	Treatment Failure Rate in Intensive Treatment Group	Death or Severe Disability at 3 Months
INTERACT2	150-200	Intensive: < 140 Guideline: < 180	Within 6 hours from symptom onset	Intensive: 150 Guideline: 164	67%	Intensive: 52.9% Guideline: 55.6% *P* = 0.06
ATACH2	≥ 180	Intensive: 110-139 Standard: 140-179	Within 4.5 hours of symptom onset	Intensive: 141.1 Standard: 128.9	12.2%	Intensive: 38.7% Guideline: 37.7% *P* = 0.72

ATACH2. The modified Rankin scale score assesses disability and dependence in daily activities and ranges from 0-6 (0 = no symptoms; 1 = symptoms, but no significant disabilities; 2 = slight disability, able to look after one's own affairs without assistance; 3 = moderate disability, able to walk without assistance; 4 = moderate to severe disability, unable to walk and attend to own bodily needs without assistance; 5 = severe disability, bedridden and requiring constant nursing care; and 6 = death).

In INTERACT2, 52% of subjects in the intensive treatment group and 55.6% in the guideline treatment group died or were severely disabled at three months. This difference did not quite meet statistical significance (odds ratio [OR], 0.87; 95% confidence interval [CI], 0.75-1.01; *P* = 0.06). However, in a secondary outcome measure, Rankin scores were ranked rather than dichotomized. Ranking provides increased power to detect a true difference between study arms. Using ranked scores, intensive treatment was associated with a significantly favorable shift in the distribution of scores (pooled OR, 0.87; 95% CI, 0.77-1.00; *P* = 0.04). This essentially means that more patients who received intensive treatment received favorable modified Rankin scores. In other secondary analyses, patients in the intensive treatment group also reported fewer problems and better quality of life. There were no significant differences in adverse effects between the two groups. The authors had hypothesized that aggressive blood pressure control would lead to improved outcomes by decreasing hematoma expansion. However, the authors did not observe this. In a subgroup of patients in which the hematoma change was measured, there was no significant difference in hematoma expansion (absolute change, 1.4 mL; 95%CI, -0.6 to 3.4; *P* = 0.18). Overall, INTERACT2 generally was viewed as a positive study, given the near significant difference in primary outcome, the favorable phase shift in ranked modified Rankin scores, and the lack of adverse events associated with intensive blood pressure control in ICH. Since half of patients were not randomized until after four hours and administered the modest decrease in blood pressure achieved, many believed that earlier and more aggressive blood pressure control would produce an even more impressive improvement in outcomes. However, despite achieving these goals in ATACH2, intensive treatment of blood pressure was not associated with better outcomes.

The creators of ATACH2 intended to enroll 1,280 participants but ended the trial early after 1,000 patients were enrolled due to futility. Death or disability was observed in 38.7% of patients in the intensive treatment group and 37.7% of patients in the standard treatment group (relative risk [RR], 1.04; 95% CI, 0.85-1.27; *P* = 0.72). When modified Rankin scores were ranked, there also was no significant difference between the two study groups. Intensive blood pressure treatment was associated with more serious adverse events within three months (RR, 1.30; 95% CI, 1.00-1.69; *P* = 0.05). There were no differences in quality of life. Similar to INTERACT2, there was no significant difference in hematoma expansion.

CONCLUSIONS

INTERACT2 and ATACH2 were the types of trials ICU clinicians seek: large, well-designed, randomized, controlled trials addressing a relevant clinical question. However, despite these publications, clinicians remain left to weigh the results of a seemingly positive study with a negative study that ended early due to futility. Although not definite, results seem to suggest that moderate blood pressure control following spontaneous ICH, targeting a SBP of 140-150 mmHg, may provide benefit. INTERACT2 suggested that a blood pressure of 150 mmHg (intensive treatment) was better than 164 mmHg (guideline treatment). In ATACH2, the blood pressure in the

standard treatment group (mean SBP 141.1 mmHg) was similar to the intensive treatment group of INTERACT2. Pushing blood pressure lower, as in the intensive treatment group in ATACH2 (mean SBP 128.9 mmHg), does not seem to provide added benefit, possibly harm. This idea of moderate blood pressure control following ICH, with a goal SBP of around 140 mmHg[8] or 140-180 mmHg,[9] has been recommended by others following these publications as well. A moderate rather than an intensive blood pressure goal may have implications beyond just the individual patient. Targeting a more moderate reduction in blood pressure may avoid the need for IV drips, thus allowing for an earlier transfer out of the ICU or avoidance of some ICU admissions altogether. Furthermore, moderate blood pressure control was not associated with an increase in adverse events in INTERACT2.

If blood pressure control leads to better outcomes, the mechanism through which this occurs remains unanswered. It does not seem to be through preventing hematoma expansion. In both studies, hematoma expansion was not affected by blood pressure control. Other factors, such as anticoagulation or location of the hemorrhage, may be more important determinants of hematoma expansion. Finally, it is important to remember that patients who presented in a deep coma, with large hematomas, with intracranial pressure elevation, or with hemorrhage due to trauma, were excluded from both trials. Very few patients were on anticoagulation, and virtually all bleeds were supratentorial. Results from INTERACT2 and ATACH2 may not apply to these patients, and the optimal blood pressure in these situations remains undetermined. ■

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ABSTRACT & COMMENTARY

Antibiotic Treatment in Community-acquired Pneumonia

By Kathryn Radigan, MD

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Dr. Radigan reports no financial relationships relevant to this field of study.

SYNOPSIS: In patients with newly diagnosed community-acquired pneumonia, basing the duration of antibiotic treatment on clinical stability criteria led to a significant reduction in duration of antibiotic treatment without an increased risk of adverse outcomes.

SOURCE: Uranga A, España PP, Bilbao A, et al. Duration of antibiotic treatment in community-acquired pneumonia: A multicenter randomized clinical trial. *JAMA Intern Med* 2016;176:1257-1265.

Although the Infectious Diseases Society of America (IDSA)/American Thoracic Society (ATS) guidelines suggest a minimum of five days of treatment in patients with one or more community-acquired pneumonia (CAP)-associated instability criteria and who achieve an afebrile state for 48-72 hours, the optimal length of antibiotic treatment has not been formally investigated. To determine whether the duration of antibiotic treatment based on IDSA/ATS criteria was as effective as conventional treatment, Uranga et al conducted a multicenter, non-inferiority, randomized, clinical trial performed at four teaching hospitals in Spain. From Jan. 1, 2012, through Aug. 31, 2013, 312 hospitalized patients

diagnosed with CAP were randomized to an intervention or control group on day five of their hospitalization. Pneumonia was defined as a new pulmonary infiltrate on chest X-ray in addition to at least one symptom compatible with pneumonia, including cough, fever, dyspnea, and/or chest pain. Patients were excluded if they were infected by HIV, exhibited chronic immunosuppression, resided in a nursing home or previously were in an acute care hospital/palliative care unit, ingested antibiotics within the previous 30 days, required a longer course of antibiotics based on identification of bacteria, required a chest tube, or presented with extrapulmonary infection. For patients randomized to the intervention group, treatment with antibiotics continued for a minimum of five days, with cessation of treatment at that time if their body temperature was ≤ 37.8°C for 48 hours and they had ≤ 1 CAP-associated sign of clinical instability. Signs of CAP-associated instability included systolic blood pressure < 90 mmHg, heart rate > 100 beats per minute, respiratory rate > 24 per minute, arterial oxygen saturation < 90%, or PaO_2 < 60 mmHg on room air. Physicians determined the length of antibiotics in the control group. In both groups, physicians chose the type of antibiotic based on local guidelines. Main outcomes included clinical success rate at days 10 and 30 from hospital admission and CAP-related symptoms at days five and 10 (measured by the 18-item CAP symptoms questionnaire score, range 0-90).

Of the 312 patients who were enrolled, 150 patients were randomized to the control group and 162 to the intervention group. When comparing groups, there were no significant differences in age or sex distribution. The number of days receiving antibiotics was significantly longer for patients in the control group compared to the intervention group (median 10; interquartile range [IQR], 10-11 vs. median 5; IQR, 5-6.5 days, respectively; $P < 0.001$). An intention-to-treat analysis comparing patients at day 10 demonstrated clinical success of 48.6% (71 of 150) in the control group and 56.3% (90 of 162) in the intervention group ($P = 0.33$). There were no differences in clinical success between the control and intervention groups at day 30. At day five and day 10, the mean CAP symptom questionnaire scores were 24.7 (standard deviation [SD], 11.4) vs. 27.2 (SD, 12.5) and 18.6 (SD, 8.5) vs. 17.9 (SD, 7.4), respectively ($P = 0.69$). For the per-protocol analysis, clinical success was 50.4% (67 of 137) in the control group and 59.7% (86 of 146) in the intervention group at day 10 ($P = 0.12$). At day 30, clinical success was 92.7% (126 of 137) in the control group and 94.4% (136 of 146) in the intervention group ($P = 0.54$). At day five and day 10, the mean CAP symptoms questionnaire scores were 24.3 (SD, 11.4) vs. 26.6 (SD, 12.1) and 18.1 (SD, 8.5) vs. 17.6 (SD, 7.4), respectively ($P = 0.81$). The researchers agreed that basing the duration of antibiotic use on clinical stability criteria can be safely implemented in hospitalized patients presenting with CAP.

■ COMMENTARY

Even though CAP is one of the leading causes of morbidity and mortality,[1] the optimal duration of antibiotic treatment for CAP is unknown. For years, it was standard to treat patients until a clinical response occurred. Typically, this resulted in antibiotic length of therapy less than four days.[2] With the growing concern for antibiotic resistance after World War II, doctors increasingly were concerned about relapse of pneumonia and treated for an additional two to three days after resolution of symptoms. Unfortunately, this practice led to the philosophy that treating beyond resolution of symptoms could prevent antibiotic resistance. This mindset translated into common practice until 2007 with the release of the IDSA/ATS guidelines. These guidelines suggested five days of treatment in patients who were afebrile for 48-72 hours and exhibited no signs of clinical instability. Although many entertained these recommendations, they were not widely adopted.

To further investigate the optimal length of antibiotic treatment for CAP and support the IDSA/ATS guidelines, Uranga et al conducted a multicenter, non-inferiority, randomized, clinical trial that included 312 hospitalized patients diagnosed with CAP. At day five, patients were randomized either to an intervention group that limited antibiotics to five days as long as body temperature was ≤ 37.8°C for 48 hours with ≤ 1 CAP-associated sign of clinical instability or to antibiotics per determination of the caring physician. Through these inventions, researchers discovered there was no significant difference in either the clinical success rate or the CAP symptom questionnaire scores. Since this study was a non-inferiority study, its creators did not address specific benefits of shortened length of antibiotic therapy. For instance, the literature says that shortened length of antibiotics lead to lower rates of antibiotic resistance.[3] Reduced duration of antibiotics also may lead to improved adherence, decreased incidence and severity of side effects, and cost savings.[4,5]

Before widely adopting these guidelines, one should be aware of the exclusion criteria that may make this study inapplicable for many patients. These exclusion criteria were extensive and included patients with HIV or chronic immunosuppression (comprising solid organ transplant patients, patients post-splenectomy, taking ≥ 10 mg of prednisone daily or the equivalent for 30 days, on other immunosup-

pressive agents, demonstrating neutropenia); patients residing in nursing homes; patients discharged from acute care hospitals, onsite subacute care units, or palliative care units within the previous 14 days; and/or patients who had ingested oral antibiotics within 30 days of admission, required longer duration of antibiotics based on cause, required a chest tube, acquired an extrapulmonary infection, or transferred to the ICU prior to randomization. Depending on the site of practice, these exclusion criteria may include the majority of one's patient population. It also may be important to note that 80% of patients received a fluoroquinolone, and it is unclear if these same results would be appreciated with alternative antibiotic regimens.

The IDSA/ATS recommendations for shorter duration of antibiotic treatment based on clinical stability criteria can be safely implemented in hospitalized patients with CAP. It should be noted that these recommendations must be applied safely, ensuring that the exclusion criteria of this study are respected. Future studies are needed to further delineate the benefits of shorter antibiotic courses. ■

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ABSTRACT & COMMENTARY

Strategies to Manage the Failed Airway

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Dr. Niven reports no financial relationships relevant to this field of study.

SYNOPSIS: In this large, multicenter, retrospective study, video laryngoscopy, the most common approach to failed airway management, demonstrated a high rate of success, even when difficult ventilation existed.

SOURCE: Aziz MF, Brambrink AM, Healy DW, et al. Success of intubation rescue techniques after failed direct laryngoscopy in adults. *Anesthesiology* 2016;125:656-666.

The failed airway, generally defined as clinical factors that complicate intubation or effective ventilation, is associated with significant morbidity and mortality. Current difficult airway guidelines recommend a systematic approach to airway assessment, patient and equipment preparation, and procedure planning to increase the rate of first attempt intubation success. However, the best rescue technique to manage the failed airway is less clear, and current data are limited to single center experiences, with little direct comparison between procedures.

Aziz et al wanted to determine the comparative effectiveness of five intubation rescue techniques suggested by the American Society of Anesthesiologists Difficult Airway Algorithm (video laryngoscopy, flexible fiberoptic laryngoscopy, lighted stylet, optical stylet, or supraglottic airway [SGA] as a conduit to intubation), and to test the hypothesis that video laryngoscopy (VL) was associated with a higher rate of success than other techniques.

The authors used a multicenter, retrospective, observational design made up of nine years of data from seven large U.S. tertiary care academic institutions compiled by the Multicenter Perioperative Outcomes Group. Electronic records from all adults with an unsuccessful tracheal intubation attempt using direct laryngoscopy (DL) followed by one of the five techniques of interest were included. The use of a bougie or introducer with DL was not included unless the DL attempt was abandoned. The primary outcome was the rate of successful intubation using each rescue technique. Secondary outcomes included success rates in difficult or impossible mask ventilation and associated airway complications.

A total of 1,427 cases met inclusion criteria from 346,861 electronic case records. Cases were managed by attending anesthesiologists, anesthesia residents, and certified nurse anesthetists, and most rescue intubations occurred after only one failed DL attempt (68%).

VL was the most common rescue technique (69%), followed by flexible fiberoptic intubation (11%), lighted stylet (8%), optical stylet (8%), and SGA (5%). The success rate with VL was very high (1,032 of 1,122 cases, 92% confidence interval [CI], 90-93%) and superior to all other techniques (77-78% for all methods, except 67% for optical stylet; $P < 0.001$ for all). Most VL cases employed a GlideScope (89%), Storz DCI or C-MAC (6%), or Bullard scope (4%), with similar high success rates (90-92%). Interestingly, VL was the preferred tool to intubate patients with difficult or impossible mask ventilation (107 of 155 cases, 69%) with equivalent success rates when compared to a SGA (88% vs. 83%; P = NS).

When VL was unsuccessful, airways were most often managed using flexible fiberoptic intubation (37.5%) or by return to DL with a bougie (18.75%). Although 52% of these airway management cases were associated with hypoxemia, difficult mask ventilation, or two failed DL attempts, only 28% had identified high-risk preoperative airway exam findings. Hypoxemia (SpO_2 < 90% for more than one minute) occurred in 25% of rescue attempts, and rare pharyngeal injuries (12 cases) occurred only with the use of VL.

■ COMMENTARY

The authors' conclusions support several well-documented principles associated with difficult airway management. The poor observed performance of the preoperative airway exam reminds us that anatomic findings alone are poor predictors of the difficult airway and must be combined with measures of physiologic derangement and operator experience using tools such as the MACOCHA Score to increase sensitivity in the ICU.

Aziz et al noted that operators frequently resorted to a rescue technique after only one DL attempt, and the utilization of VL in this setting tripled between 2004 and 2012. This trend reflects the growing availability of VL devices in operating rooms and ICUs and increasing familiarity with their use as both primary and rescue airway tools. As VL provides better glottic visualization over DL, it is logical that providers practiced in regular VL use would utilize this technique in high-pressure, failed airway situations with significant success.

It is important to note that the addition of a bougie to DL was employed successfully to rescue the vast majority of failed airways in another large single-institution study of urgent airway management. The decision to exclude these cases in the current analysis raises concerns that the role of VL potentially is over-represented in this series. The small but associated incidence of pharyngeal injury with VL observed also is an important reminder that VL blades should be placed into the oropharynx under direct visualization prior to shifting attention to the video monitor.

VL was used frequently and successfully in failed airways in which ventilation is difficult, a situation in which current guidelines still recommend early SGA use to preserve oxygenation. The explanation of this surprising finding is less clear but underlines the weak evidence that supports this recommendation and the need for a prospective randomized trial to more effectively address this question.

This study demonstrates that providers are reaching for VL as a primary rescue tool for failed airways early and often as availability and facility have grown and with a high degree of success. This observation suggests that operators appropriately reach for the tools with which they are most comfortable in a crisis, but also emphasizes the need for better comparative studies to determine how best to employ the growing array of available advanced airway tools and better inform our guidelines for difficult airway management. ■

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CME/CE QUESTIONS

1. **In ATACH2, early and aggressive treatment of systolic blood pressure after intracerebral hemorrhage was associated with:**
   a. an increased risk of death.
   b. no difference in the proportion of patients with death or severe disability.
   c. an increased risk of stroke due to peri-hematoma ischemia.
   d. severe hypotension leading to renal failure.

2. **Which of the following statements is true?**
   a. The goal systolic blood pressure (SBP) for patients in the intensive treatment group in INTERACT2 was < 140 mmHg.
   b. Very few patients in the intensive treatment group met the treatment SBP goal at one hour in INTERACT2.
   c. There was no significant difference in the primary outcome measure of proportion of patients who died or had a significant disability in either INTERACT2 or ATACH2.
   d. All of the above

3. **In the study by Uranga et al, length of antibiotic therapy in uncomplicated community-acquired pneumonia should be:**
   a. based on clinical stability criteria.
   b. seven days.
   c. 14 days.
   d. 21 days.

4. **Which of the following techniques was associated with the greatest success to rescue a failed airway in the study by Aziz et al?**
   a. Video laryngoscopy
   b. Flexible fiberoptic laryngoscopy
   c. Lighted stylet
   d. Optical stylet

5. **Based on current guidelines, what is the recommended initial rescue technique for patients with failed airways who are difficult to ventilate?**
   a. Bag valve mask
   b. Direct laryngoscopy
   c. Supraglottic airway
   d. Video laryngoscopy

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- identify relevant topics in the practice of critical care medicine;
- utilize recommendations from current clinical guidelines; and
- manage common critically ill patient and ICU administration scenarios.

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