**Safety of a High-Dose Tranexamic Acid Protocol in Complex Adult Spinal Deformity: Analysis of 100 Consecutive Cases**

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**STRUCTURED ABSTRACT**

**Study Design:** Retrospective review of high-dose tranexamic acid (TXA) use in consecutive patients.

**Objective:** To determine the safety profile of a high-dose TXA protocol in complex adult spinal deformity patients.

**Summary of Background Data:** Adult spinal deformity (ASD) surgery may involve significant amounts of blood loss, especially when various osteotomy techniques are utilized. Antifibrinolytic agents such as TXA have been used to reduce intraoperative blood loss. However, there is no universally accepted dosing protocol for its use during complex ASD surgery.

**Methods:** Consecutive patients undergoing spinal deformity correction over a 14-month period at a single institution were identified. Inclusion criteria were adults (age >= 18 years) who underwent posterior spinal fusion of at least 5 levels and use of our standard TXA protocol of 50 mg/kg intravenous loading dose followed by a 5 mg/kg/hr infusion until skin closure. Patient demographics, estimated blood loss (EBL), operative time, transfusion rates, complications and other procedure specific information were recorded.

**Results:** A total of 100 adult patients were included. All operative procedures were performed by the senior surgeon. The mean age was 47.3 years, and 71% of patients were female. Average BMI was 24.9. The average fusion length was 14 levels; 33/100 patients had fusion constructs 17 levels or more. Pedicle subtraction osteotomy (PSO) was performed in 9 patients and vertebral column resections (VCRs) were performed in 14 patients. There were 45/100 patients who had a primary procedure, while the rest were revisions. Mean EBL was 1336 mL (98 mL/level, 31% EBV). There were three thromboembolic complications including one PE and two DVTs, which were all treated successfully with anticoagulation. There were no cases of MI, seizure, stroke, or acute renal failure.

**Conclusions:** This is the first study to demonstrate the use of high-dose TXA in a complex ASD population. Larger prospective studies are needed to assess the efficacy and safety of high dose TXA in ASD.

**Level of Evidence:** Level IV, Therapeutic

**MANUSCRIPT**

**Introduction**

Adult spinal deformity (ASD) surgery can be associated with significant blood loss due to various factors such extensive soft tissue dissection, long segment instrumentation, epidural bleeding from multi-level neural element decompression, as well significant blood loss that can occur during osteotomies.[1-3](#_ENREF_1) Increased blood loss has both direct and indirect effects on the clinical outcome. The direct effects of significant blood loss include hemodynamic instability, end organ dysfunction from hypoperfusion, and coagulopathy from loss of clotting factors and platelets, as well activation of fibrinolysis pathway. Indirect effects of blood loss include complications inherent to blood transition such as transfusion reaction, hypersensitivity, acute lung injury, and increased risk for infection.[1](#_ENREF_1),[4](#_ENREF_4)

Various strategies have been utilized by spine surgeons to reduce blood loss in an effort to minimize the complications associated with blood loss. These strategies include hypotensive anesthesia during exposure, hemodilution, intraoperative cell salvage system, and pharmacological agents. Tranexamic acid (TXA) is a synthetic anti-fibrinolytic amino acid used in various surgical fields including cardiac, transplant, gynecologic, orthopaedic and spinal surgery.[2](#_ENREF_2),[5](#_ENREF_5) It is a lysine analog that reversibly binds receptor sites on plasma and plasminogen to inhibit plasminogen activation.[5](#_ENREF_5),[6](#_ENREF_6) Multiple studies have documented TXA usage resulting in significant decrease in intraoperative blood loss during spinal surgery. [2](#_ENREF_2),[7-12](#_ENREF_7)

Various TXA dosing regimens have been reported in the spine surgery literature with no established guidelines. Dosing ranges from a single dose of 15 mg/kg to a very high dose regimen of 100 mg/kg loading dose followed by 10 mg/kg/h infusion during surgery until skin closure. [2](#_ENREF_2),[8](#_ENREF_8),[13](#_ENREF_13) There have been very few reports of high-dose (>50 mg/kg) TXA usage in ASD.[2](#_ENREF_2),[12](#_ENREF_12)

The potential adverse effects of using TXA have been a major concern for clinicians, especially when high-doses of TXA are used in elderly patients. TXA has been shown to decrease seizure threshold in patients undergoing cardiac surgery.[14](#_ENREF_14) It also has the theoretical risk of thromboembolic disease, although a recent systematic review of randomized trials showed thromboembolic complications to be very rare.[12](#_ENREF_12) Case reports exist for cerebral thrombosis, arterial thrombosis, and acute renal failure, but these events are rare as well.[6](#_ENREF_6)

The high-dose TXA dosing protocol at our institution was jointly determined by the spine and anesthesia departments to be a 50mg/kg loading dose followed by a 5mg/kg/hr infusion. This dosing was felt to be a compromise between the efficacy of the 100mg/kg dosing reported in pediatric spinal deformity, while being below the high dosages associated with seizures in the cardiac literature. It has been demonstrated in the cardiac literature that high-dose TXA (>=100mg/kg) use is associated with post-operative seizures.[15](#_ENREF_15) This dosage has also been previously studied and reported on in the cardiac and obstetrical literature.[16](#_ENREF_16),[17](#_ENREF_17)

We aim to investigate the efficacy and safety profile of a high-dose TXA protocol (loading dose of 50 mg/kg followed by 5 mg/kg/hr infusion until skin closure) in ASD patients at our institution over a 14-month period with a review of pertinent literature.

**Material and Methods**

*Study Design*

Patients who underwent ASD surgery at a single institution between September 2015 to November 2016 were identified. Inclusion criteria were adults (age >= 18 years old) with spinal deformities such as scoliosis, kyphosis and flatback syndrome, who had underwent posterior spinal fusion surgery of at least 5 levels and use of our standard TXA protocol of 50 mg/kg intravenous loading dose followed by a 5 mg/kg/hr infusion until skin closure. Patient demographics, medical co-morbidity, procedure type, fusion levels, osteotomy type and levels, estimated blood loss, cellsaver collection, intraoperative and postoperative blood transfusion requirement, as well as complications such as MI, ARF, stroke, seizure, DVT and PE in the perioperative period were recorded. Estimated blood volume was calculated as the patient’s weight (in kilograms) x 70mL/kg. Patients who had staged 3-column osteotomies (3CO) were counted as two separate procedures with the osteotomies attributed accordingly.

*Anesthetic Technique*

A similar anesthetic technique was used in all patients. Patients were premedicated with midazolam (1-4 mg) and fentanyl (50-150 mcg). General anesthesia was induced with propofol (1.5-2.5 mg/kg), lidocaine (50-100 mg), and rocuronium (30-40 mg) or succinylcholine (120-200mg) to facilitate intubation. Anesthesia was maintained with propofol (60-200 mcg/kg/min) and remifentanil (0.1-0.8 mcg/kg/min). Depth of anesthesia was monitored by vital signs and bispectral index monitoring.

TXA was given as a bolus of 50mg/kg after induction and before incision, followed by a continuous infusion of 5mg/kg/h during the whole procedure until wound was closed. Mean arterial pressure (MAP) was maintained at 70mmHg during the dissection phase until spine was exposed, and MAP was raised to 90 mmHG during the correction phase of surgery. MAP was raised to higher mean pressures if there were any changes in SSEP or MEP. Transfusion threshold was not rigidly defined. Usually blood was transfused or cell saver given once HCT was below 25. Transfusion threshold depended on the anesthesiologist and surgeon’s decision and on patient’s co-morbidities.

*Intraoperative Coagulation Devices*

In all cases, meticulous exposure of the spine is performed by the senior author and a spine surgery fellow with standard monopolar electrocautery set at 65 watts and bipolar cautery set at 65 watts.

*Prevention of DVT/PE*

Pneumatic compression stockings were used post-operatively and all patients were examined for clinical signs and symptoms of DVT or PE. Additional tests such as LE Doppler and CTA chest were ordered as clinically indicated. If patient had a previous history of DVT or PE, a prophylactic IVC filter was placed.

*Statistical Analysis*

Distribution of variables is presented as mean and standard deviation (+/-). The student t-test was used to determine clinical significance between groups. A p-value of <0.05 was considered statistically significant. Patients were separated into two groups for analysis: patients without a 3CO versus those with a 3CO who had either a pedicle subtraction osteotomy (PSO) or a vertebral column resection (VCR).

**Results**

A total of 101 consecutive adult patients had undergone spinal deformity surgery performed by a single surgeon during the study period with the high-dose TXA protocol. One patient (Jehovah’s Witness) was excluded due to use of a higher dose than our typical protocol (100mg/kg loading dose followed by a 10 mg/kg/hr infusion) due to the patient’s refusal of any blood transfusions. No other patients were excluded from analysis.

The mean age was 47.3 +/- 19.4 years (range, 18-75 years) with 71 out of 100 patients being female. The mean BMI was 24.9 +/- 5.7 (range, 15.1-43.7) and the average extent of fusion was 14 levels +/- 4.5 (range, 5 to 24 levels). 33/100 patients had fusion constructs 17 levels or greater (Figure 1). PSOs were performed in 9 patients, and VCRs were performed in 14 patients. One PSO and two VCRs were staged. 45 patients had no prior spinal surgery, while the other 55 patients had prior spinal surgeries. Pelvic fixation was utilized in 63 patients, and 54 patients had at least one level transforaminal lumbar interbody fusion (TLIF).

Average operative time was 472.2 +/- 138.6 minutes (range, 179-853 minutes). Patients in the 3CO group had significantly longer operative compared to the no 3CO group (p<0.001). (Table 1)

Mean intraoperative blood loss among all patients was 1336 +/- 754 mL (range, 100-4000 mL). As a percentage of estimated blood volume (EBV), intraoperative blood loss was 30.8 +/- 17.2% (range, 2.4-81.0%). There were 52/100 patients who required transfusion intra-operatively, and 73/100 patients required a transfusion during the hospital stay. The mean cellsaver collection was 411 +/- 296 mL (range, 0-1500 mL). There was significantly greater intraoperative blood loss, intraoperative transfusion, and total transfusion requirements in patients who underwent a 3CO. (Table 2) Importantly, no patient developed any perioperative coagulopathy as evidenced by an absence of any platelets or FFP transfused perioperatively.

There were 21 total complications. The majority of the complications (18 out of 21) were not related to TXA use. These including six patients with wound related issues, six incidental durotomies repaired intraoperatively without sequelae, one patient with proximal junctional kyphosis requiring revision surgery, one case of proximal junctional failure after a fall at a rehab facility, three patients with postoperative neurological deficits that required return to the OR. Three complications were potentially attributable to TXA use and these included one patient with a PE and two patients with DVTs that developed in rehab, all which were treated successfully with anticoagulation. There were no cases of MI, seizure, stroke, or acute renal failure.

**Discussion**

The aim of this study is to examine the safety profile of a high-dose TXA protocol (50 mg/kg loading dose followed by a 5 mg/kg/hr infusion) in a series of complex ASD patients.

In this series, there were only three complications (3%) potentially attributable to TXA in the perioperative period including one PE and two DVTs all treated without any major sequelae. There were no other TXA-related complications such as MI, seizure, stroke, or acute renal failure in this group of patients. The overall average blood loss was 1336 mL, and not surprisingly, there was significantly greater blood loss in patients with 3COs versus those without (1198 +/- 638 mL vs 1825 +/- 931mL, p<0.001). The average amount of blood transfusion was 815 mL with 27% of patients avoiding any transfusion during the hospital admission. As would be expected, patients who had a 3CO had a significantly greater transfusion volume (1190 +/- 681 mL vs 709 +/- 660 mL, p=0.006), and a higher proportion of patients requiring transfusion during the hospital stay (91% vs 68%, p=0.032). Of note, no patients in this series required platelets or FFP transfusion perioperatively.

The demographic characteristics of this series highlight the complexity of this adult deformity series especially when compared to other studies in the literature on TXA use in spinal deformity, with mean age of 47.3 years, average of 14 levels fused, and 22/100 patients with 3COs, including nine patients with PSOs and 14 patients with VCRs (as shown in Table 4). Nevertheless, the mean intraoperative blood loss appears to be less compared to existing literature where >4L of blood loss can be see in up to 24% patients with 3COs.[18](#_ENREF_18)

There are several reports of low-dose TXA usage in adult spine surgery demonstrating it has limited efficacy. Wong et al reported on a randomized trial of 151 adult patients comparing placebo versus TXA versus at 10mg/kg loading followed by a 1mg/kg/hr infusion. They found a significantly less perioperative blood loss in the TXA group, but no difference in blood products transfused.[11](#_ENREF_11)

Baldus et al reported on a retrospective review of 44 ASD patients undergoing lumbar PSO. There were 10 patients in the control group, 14 patients in the aprotinin group, and 20 patients in the TXA group. The TXA dosing was a 10mg/kg loading dose followed by a 0.5 mg/kg/hr infusion. They found the aprotinin group had significantly less blood loss and transfusions than the TXA or control group. They did not find a difference between the TXA and control group with respect to blood loss or transfusions. The mean age of TXA group was 54 years, with an average of 7.6 levels fused. The mean EBL in this series was 2102 mL and mean blood transfused was 1838 mL.[1](#_ENREF_1) Our series compares favorably with less blood loss despite almost doubling the length of construct.

Peters et al reported on a randomized controlled trial compared TXA, epsilon aminocaproic acid (EACA), and placebo in 51 patients undergoing ASD surgery. TXA dosing was 10 mg/kg loading dose followed by a 1mg/kg/hr infusion. They showed that EACA significantly reduced perioperative bleeding, while TXA group showed a non-significant reduction in blood loss compared to the control group. There were 19 patients in the TXA group with mean age of 60 years, a mean of 11 levels fused, mean EBL of 1400 mL (130/level), and a 74% intraoperative transfusion rate and 53% postop transfusion rate. It was not reported whether any 3COs were represented in the group. Their results are consistent with findings from our study.

There are several studies reporting the efficacy of high-dose TXA usage in the pediatric spine literature. Sethna et al conducted a RCT of high dose TXA (100mg/kg followed by 10/mg/kg infusion) in pediatric scoliosis surgery in 44 patients. They found that blood loss was significantly reduced in the TXA group.[7](#_ENREF_7) Shapiro et al reported on a retrospective review 56 patients undergoing spinal fusion for Duchenne’s muscular dystrophy. There were 20 patients that received the high dose TXA at 100mg/kg loading and 10mg/kg infusion, and while TXA was not used in 36 patients. The TXA group had significantly less blood loss and transfusion requirements.[8](#_ENREF_8) Xie et al reported of 59 patients undergoing spinal deformity correction. There were 27 pediatric patients in this group. The TXA group received a 100mg/kg loading dose followed by 10mg/kg/hr infusion. They found the TXA group to have significantly less blood loss and transfusion requirements. The mean age of the TXA group was 18.9 years, with a mean of 13 levels fused, the mean EBL was 2441mL, and the mean quantity of blood transfusion was 1750 mL. There were no complications attributable to TXA reported in any of these three high-dose studies.

The lack of data regarding high dose TXA in the ASD population is likely due to the concerns for thromboembolic events and seizures associated with high-dose TXA. While there is a theoretical concern of increased risk of thromboembolic events secondary to TXA usage, this has not been demonstrated in the literature.[5](#_ENREF_5),[12](#_ENREF_12),[19](#_ENREF_19) A recent systematic review of 11 RCTs involving TXA in spinal surgery found only 1 MI and no DVT or PEs.[12](#_ENREF_12) Since the publication of that meta-analysis, Peters et al reported 1 PE in the TXA group of their RCT.[20](#_ENREF_20) In addition, TXA has been shown to decrease seizures threshold in patients undergoing cardiac surgery. [13](#_ENREF_13),[14](#_ENREF_14) The mechanism is thought to be due to blockage of cortical GABA-A receptors by TXA, a phenomena that may be exacerbated by open heart surgery. [1](#_ENREF_15)5[,21-2](#_ENREF_21)3 A retrospective review of 8929 patients undergoing cardiopulmonary bypass found that risk factors for seizure included: age >75, open heart procedure, perioperative renal failure, and TXA dose of 100mg/kg or more.[15](#_ENREF_15)

The strengths of this study are the homogenous population of ASD patients with long fusion constructs and high case complexity. It is the largest series demonstrating the use of a high-dose TXA protocol in this type of patient population. Limitations of our study include its retrospective nature and the lack of randomization or a control group. A propensity-matched cohort of patients with either low-dose or no TXA usage would be helpful to interpret the blood-loss values reported, as many factors other than antifibrinolytic dosing, such as exposure technique, surgeon experience, use of intra-operative coagulation devices, and availability of an experienced surgical fellow are likely to contribute to intraoperative blood loss. The senior author has an exclusive spinal deformity practice, performs meticulous subperiosteal exposure of the spine with monopolar electrocautery set at 65 watts with a standard bipolar cautery is at 65 watts available as needed, and is assisted by an experienced spine surgery fellow. Unfortunately, a historical control group is unavailable given that the opportunity to initiate this new protocol arose due to a change in institution by the senior author. However, the purpose of this study is to report on the safety profile of the high-dose TXA protocol in a homogeneous complex ASD population, which has not been previously reported in the literature.

**Conclusion**

This is the first study to demonstrate that high dose TXA can be safely used in complex ASD patients and lays the foundation for further studies on this important topic. Larger, prospective randomized control trials are needed to provide higher-level evidence of the efficacy and safety of high-dose TXA use in ASD.

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**Table 1. Demographic and Surgical Information.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable** | **Total** | **No 3CO** | **3CO** | **p** |
| Patients | 100 | 78 | 22 |  |
| Age | 47.3+- 19.4 (18-75) | 49.0 +- 19.0 | 41.3 +- 20.1 | 0.101 |
| Gender (F) | 71 (71%) | 58 (74%) | 13 (59%) | 0.163 |
| BMI | 24.9 +- 5.7 (15.1-43.7) | 24.7 +- 5.2 | 25.5 +- 7.2 | 0.577 |
| Levels | 14.0 +- 4.5 (5-24) | 13.7 +- 4.6 | 15.2 +- 4.2 | 0.186 |
| Estimated blood volume (EBV) | 4506.6 +- 1159.1 (2380 - 7980) | 4476.5 +- 1051.9 | 4613.5 +- 1503.8 | 0.692 |
| OR time | 472.2 +- 138.6 (179-853) | 444.4 +- 131.0 | 569.6 +- 121.9 | **<0.001** |
| Primary | 45 (45%) | 39 (50%) | 6 (27%) | 0.058 |
| Revision | 55 (55%) | 39 (50%) | 16 (73%) | 0.058 |
| VCR cases | 14 (14%) | 0 (0%) | 14 (100%) | -- |
| PSO cases | 9 (9%) | 0 (0%) | 9 (100%) | -- |
| Pelvis Fixation | 63 (63%) | 51 (65%) | 12 (54%) | 0.352 |
| TLIF | 54 (54%) | 45 (58%) | 9 (41%) | 0.163 |

**Table 2. Blood Losses and Transfusions.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable** | **Total** | **No 3CO** | **3CO** | **p** |
| Intraop BL | 1336 +- 754 (100-4000) | 1198 +- 638 | 1825 +- 931 | **<0.001** |
| Intraop BL (%EBV) | 30.8 +- 17.2 (2.4-81.0) | 28.1 +- 16.1 | 40.6 +- 17.4 | **0.002** |
| Intraop BL / Level | 98 +- 63 (13-500) | 88 +- 43 | 135 +- 100 | **0.041** |
| Intraop Transfusion | 391 +- 454 (0-1400) | 332 +- 425 | 601 +- 499 | **0.013** |
| % Intraop transfusion | 52 (52%) | 35 (45%) | 17 (77%) | **0.007** |
| Cellsaver | 411 +- 296 (0-1500) | 364 +- 245 | 578+- 395 | **0.023** |
| Total Transfusion | 815 +- 691 (0-2450) | 709 +- 660 | 1190 +- 681 | **0.006** |
| % total transfusion | 73 (73%) | 53 (68%) | 20 (91%) | **0.032** |

**Table 3. Complications.**

|  |  |
| --- | --- |
| **Complication** | **Frequency** |
| PE, started heparin drip | 1 |
| DVT after home, oral anticoag | 2 |
| Incidental durotomy | 6 |
| Superficial wound, no surgery | 3 |
| Superficial wound, surgery | 1 |
| Wound dehisce, surgery | 2 |
| PJK requiring revision surgery | 1 |
| PJF s/p fall | 1 |
| Revision decompression | 3 |
| Takusubo cardiomyopathy | 1 |

**Table 4. Comparison previously published studies on adult spinal deformity.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Journal** | **TXA dose** | **Pts** | **Age** | **Levels** | **Osteotomy** | **EBL** |
| *Lin et al* |  |  | *50/5* | *100* | *47* | *14* | *PSO/VCR (21)* | *1300* |
| Baldus et al | 2010 | Spine | 10/0.5 | 20\* | 54 | 7.6 | PSO (20) | 2102 |
| Peters et al | 2015 | Spine | 10/1 | 19\* | 60 | 11 | - | 1400 |
| Xie et al | 2015 | The Spine J | 100/10 | 26\* | 18.9 | 13 | VCR (8) | 2441 |
| Suk et al | 2005 | Spine | none | 16 | 29 | 10.6 | VCR (16) | 7034 |
| Daubs et al | 2007 | Spine | none | 46 | 67 | 9 | PSO (19) | 2056 |

\* Patients in study who received TXA

**Figure 1**

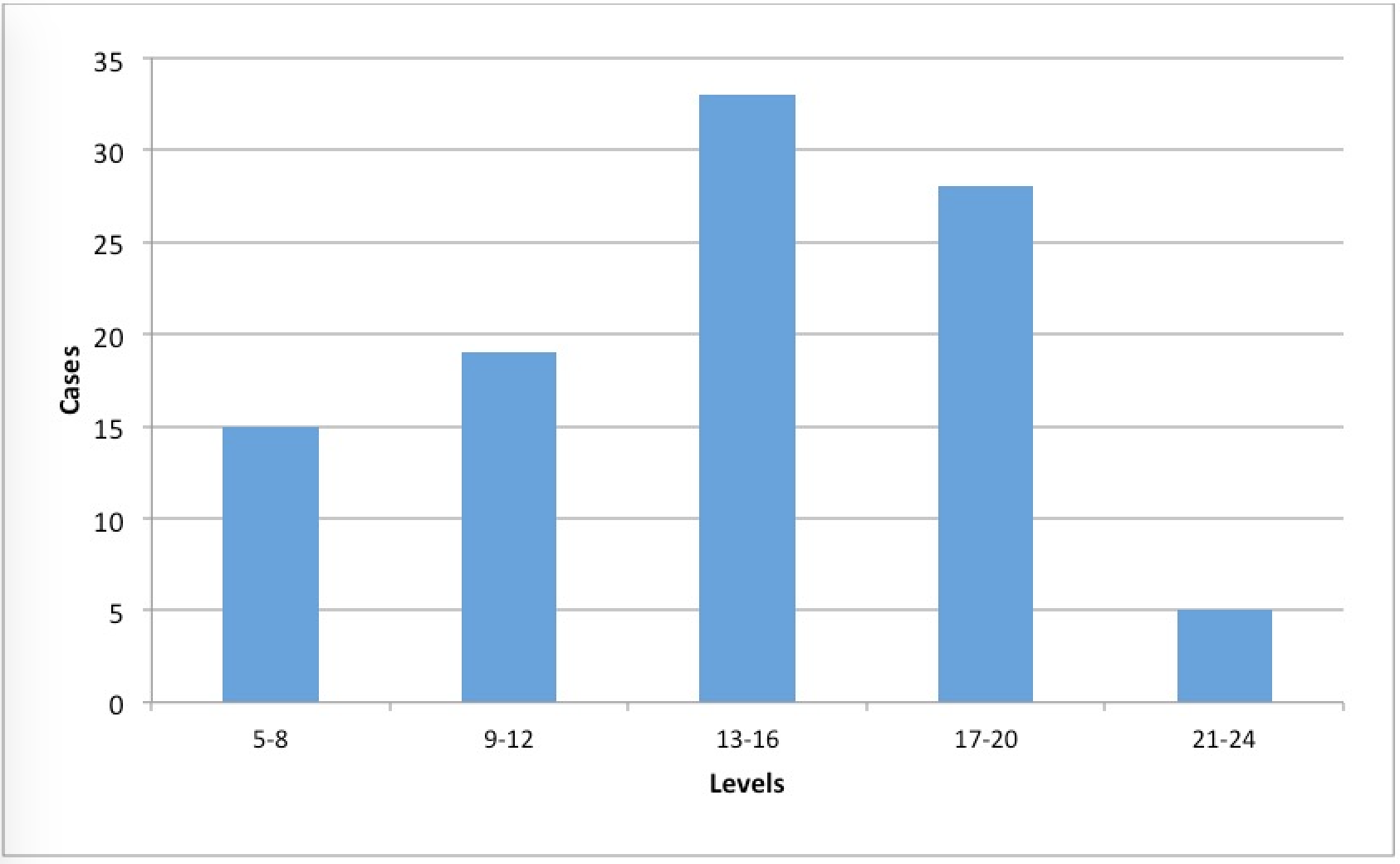


Figure 1. Distribution of cases by fusion length.